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JBP-529

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Benjamin Wiegand et al.		
Serial No.:	09/731,342	Art Unit:	1617
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For :	PERSONAL CARE FORMULATIONS		

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November 10, 2003
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James P. Barr
Name of applicant, assignee, or Registered Representative

(Signature)

November 10, 2003
(Date of Signature)

Assistant Commissioner of Patents and Trademarks
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

In accordance with the provisions of 37 CFR 1.191, Applicant filed a timely Notice of Appeal in the above application on September 8, 2003 from the rejections made by the Patent Office in the Office Action dated May 5, 2003. Three copies of the Appeal Brief are enclosed.

(1) Real Party in Interest

The real party in interest in the application in this appeal is Applicant's assignee Johnson & Johnson Consumer Companies, Inc., a corporation of New Jersey, a wholly owned subsidiary of Johnson & Johnson, a New Jersey corporation.

(2) Related Appeals and Interferences

Applicant is not aware of any related appeals or interferences.

(3) Status of the Claims

Claims 1-9 and 11-20 are the claims on appeal, a copy of which are attached hereto in the Appendix to this Brief. No claims stand allowed in this application.

(4) Status of Amendments

No amendment was made after receiving the Final rejection dated May 7, 2003. The last Amendment made in this application, dated March 5, 2003, was entered.

(5) Summary of the Invention

The present invention relates to a method of depositing a benefit agent on a keratinous surface, the method comprising topically applying to the surface an effective amount of a ringing gel composition including (a) a surfactant phase ; (b) an oil phase; and (c) a benefit agent. Suitable benefit agents include antimicrobial agents, medicament agents, skin emollients, skin moisturizers, skin firming agents, and the like.

(6) Issues on Appeal

I) Whether the inventions of claims 1-9 and 11-20 are indefinite under 35 U.S.C. §112 for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

II) Whether the inventions of claims 1, 2, 3, 11-17, and 20 are unpatentable under 35 U.S.C. §103 as being obvious over Herman in view of Santora et al. and Marin et al.

III) Whether the inventions of claims 4-9 are unpatentable under 35 U.S.C. §103 as being obvious over Herman in view of Santora et al. and Marin et al., and further in view of Greenburg et al.

IV) Whether the inventions of claims 1, 18 and 19 are unpatentable under 35 U.S.C. §103 as being obvious over Herman in view of Piechota.

(7) Grouping of Claims

Applicants believe that all of their claims are patentable over the prior art. For purposes of this Appeal, claims 1-9 and 11-20 stand together.

(8) Argument

Claims 1-9 and 11-20 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Patent Office stated that the metes and bounds of the scope of the claims are unascertainable because the terms "benefit agents", "antiinfective", "shaving preparations", "poison ivy products", "poison oak products", "burn products", "anti-diaper rash agents", "prickly heat agents", "sensates", and "make-up preparations" were not defined in the specification. Applicants respectfully traverse this rejection.

Definiteness of claim language must be analyzed, not in a vacuum, but in light of (A) the content of the particular application disclosure; (B) the teachings of the prior art; and (C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. See M.P.E.P.§ 2173.02. Here, each of the benefit agents claimed are conventional active agents used in cosmetic compositions. Indeed, as discussed in the specification, the term "benefit agent" includes any active ingredient that is to be delivered into and/or onto a keratinous surface, such as, the skin, hair or nail at a desired location. See page 3, lines 27-28.

In further support of this position, Appliacnts have provided herewith several educational references that are commonly referred to by those of ordinary skill in the art. These references specifically refer to the objected to terms utilized in the present patent application. For example, "Shaving preparations" are described in Harry's Cosmeticology - 7th edition (1982)Part One: The Skin and Skin Products - Chapter 12: Shaving Preparations, pgs. 156-187. "Make-up preparations" are also described in Harry's Cosmeticology - 7th edition (1982) Part One: The Skin and Skin Products - Chapter 17: Face Packs and Masks, Part One: The Skin and Skin Products - Chapter 18: Face Powders and Make-up,Part One: The Skin and Skin Products - Chapter 19: Coloured Make-up Preparations. "Anti-Diaper Rash Products" and "Prickly Heat Products" are described in O-T-C products for diaper rash and prickly heat. J Am Pharm Assoc. 1970 Jan;10(1):19-24. "Poison Ivy Products" and "Poison Oak Products" are described in Skin protectant drug products for over-the-counter human use; final monograph. Final rule. Fed Regist. 2003 Jun 4; 68(107): 33362-81.

In view of the foregoing, Applicants respectfully submit that the benefit agents listed in the present patent application are known and understood by those of ordinary skill in the art. As indicated above, the terms are readily found in the literature. Furthermore, many of the benefit agents are controlled through and listed in the above referenced final monograph. Applicants respectfully submit that the rejection under 35 U.S.C. §112 is incorrect and request withdrawal of the rejection.

Claims 1, 2, 3, 11-17, and 20 stand rejected under 35 U.S.C. §103 as being obvious over Herman in view of Santora et al. and Marin et al. The Patent Office relies upon Herman as disclosing the "that the basic components of ringing gel formulations are oil, water, a surfactant, and a cosurfactant." As acknowledged by the Patent Office, Herman fails to teach or suggest Applicants' claimed method of depositing a benefit agent on a keratinous surface. There is nothing in the teachings of Herman that would provide one of ordinary skill in the art with the expectation that the ringing gel composition broadly disclosed by Herman could be used to deposit benefit agents to keratinous surfaces.

Recognizing these deficiencies, the Patent Office has cited Santora and Marin et al. Santora teaches a cleansing and moisturizing surfactant composition comprising nonionic, amphoteric and anionic surfactants. Marin et al. discloses a hexagonal liquid crystal composition comprising oily phase, surfactant system and water. The compositions taught therein are disclosed as providing good viscosity, foaming, stability, appearance and cleaning ability. It is the position of the Patent Office that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the ringing gel composition of Herman to add the surfactants and cosmetic actives of Santora and Marin because of the expectation "to have successfully produced a mild and non-greasy skin or hair care composition with viscosity, stability, appearance and good cleansing effects." Applicants respectfully disagree.

The Patent Office has failed to provide any teaching or suggestion in any of the cited references that would provide one

of ordinary skill in the art with the motivation to incorporate the ingredients taught by Santora et al. into the ringing gel compositions disclosed by Herman. The Patent Office relies upon Marin as providing the requisite motivation. This position is factually incorrect. The mere fact that Marin teaches that the Marin compositions provide good viscosity, foaming, stability, appearance and cleaning ability in no way provides the requisite motivation to one of ordinary skill in the art to incorporate the ingredients taught by Santora et al. into the compositions taught by Herman, much less, that the ringing gel composition broadly disclosed by Herman could be used to deposit benefit agents to keratinous surfaces.

The Patent Office has also not provided a reasonable basis to support an expectation of success. Applicants respectfully submit that one of ordinary skill in the art would appreciate the fact that ringing gel compositions are sensitive to the concentrations of the ingredients found therein. As clearly described in Herman and as is well know to those skilled in the art, as the water, surfactant, or oil concentration of a composition is varied, the composition may change phases and no longer be a ringing gel. The use of phase diagrams is quite common in this technology. Phase diagrams typically show that as the amounts of the components of the composition are varied, the composition will change phases between two distinct phases, an oil in water emulsion, a water in oil emulsion, a ringing gel, and a microemulsion. The benefit agents that Applicants have added to the ringing gel composition may be soluble in the water or surfactant phase, the oil phase, or both. Therefore, the addition of the benefit agent effects the relative concentrations of the water or surfactant phase and the oil phase in the ringing

gel composition. Moreover, as disclosed in Applicant's specification, the addition of benefits to a ringing gel composition provided enhanced benefit deposition relative to other compositions. This was unexpected, and such benefit is not disclosed or fairly suggested in any of the cited references, taken alone or in combination. Applicants therefore respectfully submit that one of ordinary skill in the art could not predict or expect that the ringing gel composition of Herman would remain a ringing gel upon the addition of benefit agents as claimed in the present invention.

Accordingly, Applicants respectfully submit that Herman, Santora et al. and Marin, taken alone or in any combination do not render the present claims obvious for the following reasons: (1) there is no suggestion or motivation in either of Herman, Santora et al. or Marin to modify the compositions of Herman as suggested by the Patent Office; (2) even if one of ordinary skill in the art was somehow motivated to incorporate the ingredients taught by Santora et al. into the Herman ringing gel compositions, there is nothing in the teachings of Herman, Santora et al. or Marin that would provide a reasonable expectation that such a modification of the Herman ringing gel compositions would be successful; and (3) even if the references were combinable as suggested by the Patent Office, all the claim limitations are not taught or suggested since each of Herman, Santora et al. and Marin fail to teach or suggest Applicants' claimed method of depositing a benefit agent on a keratinous surface. Therefore, the rejection should be withdrawn.

Claims 4-9 stand rejected under 35 U.S.C. §103 as being obvious over Herman in view of Santora et al. and Marin et al.,

and further in view of Greenburg et al. The Patent Office relies upon Greenberg et al. for teaching the specific oil phase recited by claims 4-9. Specifically, the Patent Office argues that it would have been obvious to one of ordinary skill in the art to modify the ringing gel composition taught by Herman by incorporating certain ingredients taught by Santora et al. and further modify the composition by incorporating specific esters taught by Greenberg et al. because of "the expectation to have produced a clear microemulsion skincare composition with a smooth and non-tacky feel."

Greenberg et al. fails to remedy the deficiencies of Herman, Santora and Marin as set forth above. There is nothing in the teachings of Greenberg et al., Herman, Santora, and Marin taken alone or in any combination, that would provide one of ordinary skill in the art with the motivation to incorporate the ingredients taught by Santora et al., Marin, and Greenberg et al. into the ringing gel compositions disclosed by Herman. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. Here, the Patent Office has failed to provide the requisite motivation for the combination. Further, since neither Santora et al. nor Greenberg et al. disclose ringing gel compositions, Applicants respectfully submit that there would not be a reasonable expectation that the ingredients taught by Santora et al., Marin, and Greenberg et al. could successfully be incorporated into ringing gel compositions.

Accordingly, Applicants respectfully submit that the Patent Office has failed to establish a *prima facie* case of obviousness for the following reasons: (1) there is no suggestion or

motivation in any of the references relied upon by the Patent Office to modify the compositions of Herman as suggested by the Patent Office; (2) even if one of ordinary skill in the art was somehow motivated to incorporate the ingredients taught by Greenberg et al., Santora et al. and Marin into the Herman ringing gel compositions, there is nothing in the teachings of Greenberg et al., Herman, Marin or Santora et al., taken alone or in combination, that would provide a reasonable expectation that such a modification of the Herman ringing gel compositions would be successful; and (3) even if the references were combinable as suggested by the Patent Office, all the claim limitations are not taught or suggested since none of the references teach or suggest Applicants' claimed method of depositing a benefit agent on a keratinous surface. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Claims 1, 18 and 19 stand rejected under 35 U.S.C. §103 as being obvious over Herman in view of Piechota. The Patent Office relies upon Piechota for teaching a method for treating acne and the specific oil phase recited by claims 18 and 19. Piechota relates to topical compositions, which can be applied as a relatively low viscosity flowable liquid and which will quickly, upon contact with the warm surface of an animal, turn into a relatively high viscosity, essentially non-flowable, gel. Accordingly, the compositions taught by Piechota are distinct from the ringing gel compositions disclosed by Herman. Indeed, Piechota specifically teaches the disadvantages of compositions in the form of a gel prior to use. See col. 1, line 14 - col. 2, line 15.

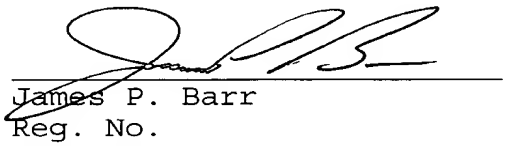
It is the Patent Office's position that it would have been obvious to one of ordinary skill in the art "to have modified the Herman's composition by adding retinoids or antimicrobial agents and used it to treat acne, as taught by Piechota, because of the expectation of successfully producing a rining gel composition that may be used for acne treatment." Applicants respectfully traverse. Why would one of ordinary skill in the art be motivated to incorporate the anti-acne ingredients taught by Piechota into the ringing gel compositions taught by Herman when Piechota specifically teaches the disadvantage of compositions that are in the form of gels prior to use when applying active ingredients to humans and animals?

The Patent Office states that Piechota discloses ringing gel compositions. Applicants respectfully disagree. References must be considered in their entirety. Clearly, Piechota is directed to compositions that are not in gel form until after applied to a desired situs. See, for example, col. 2, lines 11-15. Applicants have pointed out that the only disclosure in Piechota of ringing gels is at col. 3, lines 59-66. Here, Piechota is evaluating the effect of different poloxamers. Specifically, Piechota teaches that Pluronic F127 has the ability to form a ringing gel and as such "would not lead one skilled in the art to employ Pluronic F127 to meet the objects of this invention in that such teachings are totally inimical to the objects of this invention; it is taught that the result is a gelled solution at room temperature i.e. one that cannot be filled, stored or dispensed as a flowable liquid." See col. 3, line 66- col. 4, line 5 (emphasis added). Clearly, Piechota teaches away from compositions in the form of a gel prior to use.

The Patent Office argues that "the disadvantage of using poloxamers is irrelevant in adding acne agents or antibacterial agents into the rining gel of Herman for topical use" and that "the specific types of poloxamers referred by Piechota, Poloxamer 407, is neither a required limitation in instant claims or disclosed in Herman." Applicants respectfully submit that the Patent Office has misunderstood Applicants' arguments. Applicants have pointed to this Example as evidence that Piechota teaches that compositions for topical application in the form of gels prior to use are not desirable due to flow problems. Clearly, one of ordinary skill in the art, armed with the disclosure of Piechota, would expect that the gel compositions taught by Herman would not be useful for delivering active ingredients, such as anti-acne agents, due to the fact that they are in the form of a gel. Thus, Piechota fails to provide the requisite motivation for incorporating an anti-acne active into the compositions of Herman. Indeed, Piechota specifically teaches away from such a modification due to flow problems. Accordingly, one of ordinary skill in the art would not have been motivated to combine the teachings of Piechota with the teachings of Herman. Applicants, therefore, respectfully request that this rejection be withdrawn.

For the above reasons, Applicants respectfully request that the rejections of record be reversed and that all claims on appeal be allowed.

Respectfully submitted,



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APPENDIX

(9) Claims on Appeal

1. A method of depositing a benefit agent on a keratinous surface, said method comprising topically applying to said surface an effective amount of a ringing gel composition comprising (a) a surfactant phase ; (b) an oil phase; and (c) a benefit agent; wherein the benefit agent is selected from the group consisting of vasoconstrictors, collagen enhancers, anti-edema agents, depigmentation agents; reflectants; detangling/wet combing agents; film forming polymers; humectants; antimicrobial agents; allergy inhibitors; anti-acne agents; anti-aging agents; anti-wrinkling agents, antiseptics; analgesics; antitussives; antipruritics; local anesthetics; anti-hair loss agents; hair growth promoting agents; hair growth inhibitor agents; antihistamines; antiinfectives; inflammation inhibitors; anti-emetics; anticholinergics; vasodilators; wound healing promoters; peptides, polypeptides and proteins; deodorants and anti-perspirants; medicament agents; skin emollients and skin moisturizers; skin firming agents, hair conditioners; hair softeners; hair moisturizers; vitamins; tanning agents; skin lightening agents; antifungals; depilating agents; shaving preparations; external analgesics; perfumes; fragrances; counterirritants; hemorrhoidals; insecticides; poison ivy products; poison oak products; burn products; anti- diaper rash agents; prickly heat agents; make-up preparations; vitamins; amino acids and their derivatives; herbal extracts; retinoids; flavenoids; sensates; anti-oxidants; skin

conditioners; hair lighteners; chelating agents; cell turnover enhancers; coloring agents; pigments; sunscreens and mixtures thereof.

2. A method according to claim 1, wherein the surfactant phase comprises at least one amphoteric surfactant, at least one nonionic surfactant and at least one anionic surfactant.

3. A method according to claim 2, wherein:

(a) the amphoteric surfactant is selected from alkyl amphocarboxylates, alkyl betaines, amidoalkyl betaines, amidoalkyl sultaines, alkyl amphophosphates, alkyl phosphobetaines, alkyl pyrophosphobetaines, alkyl sulfobetaines, carboxyalkyl alkyl polyamines, and mixtures thereof;

(b) the nonionic surfactant is selected from alcohol ethoxylates, alkyl phenol ethoxylates, fatty acid ethoxylates, fatty acid monoalkylolamide ethoxylates, fatty alcohol propoxylates, fatty amine alkoxylates, fatty acid glyceryl ester ethoxylates, and mixtures thereof;

(c) the anionic surfactant is selected from alkyl sulfates; alkyl ether sulfates; alkyl monoglyceryl ether sulfates; alkyl monoglyceride sulfates; alkyl monoglyceride sulfonates; alkyl sulfonates; alkylaryl sulfonates; alkyl sulfosuccinates; alkyl ether sulfosuccinates; alkyl sulfosuccinamates; alkyl amidosulfosuccinates; alkyl carboxylates; alkyl ether carboxylates; alkyl amidoethercarboxylates; alkyl succinates; fatty acyl

sarcosinates; fatty acyl amino acids; fatty acyl taurates; fatty alkyl sulfoacetates; alkyl phosphates; alkyl isethionates, and mixtures thereof.

4. A method according to claim 1, wherein the oil phase has an HLB raging from about 3 to about 18.

5. A method according to claim 4, wherein the oil phase has an HLB ranging from about 8 to about 11.

6. A method according to claim 1, wherein the oil phase is selected from the group consisting of mineral oil, silicone oil, perfluorocarbons, alkyl esters and mixtures thereof.

7. A method according to claim 1, wherein the oil phase has a viscosity ranging from about 1 to about 500 centistokes.

8. A method according to claim 6, wherein the viscosity ranges from about 10 to about 100 centistokes.

9. A method according to claim 1, wherein said composition comprises (a) from about 60 to about 95% by wt. of the surfactant phase, based on the total composition; and (b) from about 5 to about 40% by wt. of oil the phase, based on the total composition.

11. A method according to claim 1, wherein said composition comprises from about 20 to about 70 wt. % water, based on the total composition.

12. A method according to claim 11, wherein said composition comprises from about 20 to about 50 wt. % water, based on the total composition.

13. A method according to claim 1, wherein the amount of surfactant in the composition ranges from about 10 to about 50 wt%, based on the total composition.

14. A method according to claim 13, wherein the amount of surfactant ranges from about 20 to about 45 wt. %, based on the total composition.

15. A method according to claim 1, wherein the benefit agent is present at from about 0.01 to about 10 wt.%, based on the total composition.

16. A method according to claim 1, wherein said keratinous surface is selected from the skin, hair, and/or nails of a human or animal.

17. The method according to claim 1, wherein the composition is in the form of a gel, a bath, a wash, a mousse, a shampoo, a rinse, a lotion, a cream, a wipe, a brush, a sponge, or a spray.

18. A method for treating acne of a mammal comprising topically applying, to the affected area of the skin, an effective amount of ringing gel composition comprising (a) a surfactant phase; (b) an oil phase; and (c) an anti-acne agent.

19. The method of claim 21, wherein the anti-acne agent is selected from the group consisting of benzoyl peroxide, retinol, elubiol, antibiotics, salicylic acid, and mixtures thereof.

20. A method of cleansing and delivering a benefit agent to hair, skin or nails of a mammal, comprising topically applying to a desired location an effective amount of a ringing gel composition comprising (a) a surfactant phase; (b) an oil phase; and (c) a benefit agent; wherein the benefit agent is selected from the group consisting of vasoconstrictors, collagen enhancers, anti-edema agents, depigmentation agents; reflectants; detangling/wet combing agents; film forming polymers; humectants; antimicrobial agents; allergy inhibitors; anti-acne agents; anti-aging agents; anti-wrinkling agents, antiseptics; analgesics; antitussives; antipruritics; local anesthetics; anti-hair loss agents; hair growth promoting agents; hair growth inhibitor agents; antihistamines; antiinfectives; inflammation inhibitors; anti-emetics; anticholinergics; vasodilators; wound healing promoters; peptides, polypeptides and proteins; deodorants and anti-perspirants; medicament agents; skin emollients and skin moisturizers; skin firming agents, hair conditioners; hair softeners; hair moisturizers; vitamins; tanning agents; skin lightening agents; antifungals; depilating agents; shaving preparations; external analgesics; perfumes; fragrances; counterirritants; hemorrhoidals; insecticides; poison ivy

products; poison oak products; burn products; anti- diaper rash agents; prickly heat agents; make-up preparations; vitamins; amino acids and their derivatives; herbal extracts; retinoids; flavenoids; sensates; anti-oxidants; skin conditioners; hair lighteners; chelating agents; cell turnover enhancers; coloring agents; pigments; sunscreens and mixtures thereof.

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Patents

In this book, the patent literature has been treated as a source of information. Certain formulae and processes have been included in the interests of science, notwithstanding the existence of actual or potential patent rights.

Mention of a patent does not necessarily indicate that the patent is currently in force, but in so far as materials and processes are protected by letters-patent, their inclusion neither conveys nor implies licence to manufacture. Each manufacturer should ascertain for himself the patent position existing in his own country at that time.

Legislation

Legislation concerned with permitted materials, limitations on use and methods of sale of toilet preparations is in a state of continual change, notably in the USA and the European Economic Community. While every effort has been made to take count of the latest position, inclusion of a particular ingredient in any one illustrative formula cannot be taken as indicating that this formula will be within the limits of legal permission in any one country at the time when it may be under consideration. As with patents (above) every manufacturer must ascertain for himself the legal position existing in his country or that to which he exports at that time.

Harry's Cosmeticology

Seventh edition

Edited by
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CHEMICAL PUBLISHING
NEW YORK

Preparation and Utilisation, US Dept Interior, Bureau of Mines, Washington DC, 1940.
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Chapter Eighteen

Face Powders and Make-up

FACE POWDER

Function and Properties

The function of face powder is to impart a smooth finish to the skin, masking minor visible imperfections and any shine due to moisture or grease either from perspiration or from preparations used on the skin. The object appears to be to make the skin look as though it would be pleasant to touch. The degree of opacity of the powder can vary from opaque and matt, as for example a clown's make-up, to almost transparent, which will have a type of shine due to the powder itself. Neither extreme is favoured, but between the limits, the pendulum of fashion will swing from time to time. Whatever the finish, it must possess reasonable lasting properties to avoid the need for frequent re-powdering, that is it must adhere to the skin, and be reasonably resistant to the mixed secretions of the skin. Finally, it should serve as a vehicle for a pleasing odour to be disseminated by intimate contact of perfume-laden particles over a warm and relatively large area.

No single substance possesses all the desired properties—covering power, slip absorbency, adhesiveness and bloom—hence a modern face powder is a blend of several constituents each one chosen for some specific quality. The various properties will now be considered in greater detail together with some of the principal ingredients, arranged according to their various functional contributions to the powder base. These properties are included in the section on face powders mainly for historical reasons. The popularity of face powders has declined considerably in recent years in favour of compact powders, foundation and liquid make-up. However, the materials and principles involved are equally applicable to these products so a careful study of the following sections will benefit the formulator in his or her work on more sophisticated products.

Covering Power

Good covering power is a very desirable attribute of face powders, its object being to conceal various defects of the facial skin including scars, blemishes, enlarged pores and excessive shine.

Titanium dioxide, zinc oxide, kaolin and magnesium oxide are the materials used to enhance the covering power of face powders.

Titanium Dioxide

Titanium dioxide has considerably greater covering power *per se* than zinc oxide, about 1·6 times that of the latter in air and about 2·9 times the latter in

petroleum jelly. On a moist greasy skin, its covering power relative to zinc oxide is probably of the order of 2·5 times. Titanium dioxide is not astringent but is physiologically inert and may be found, in any rare cases of allergy to zinc compounds or in cases of dry skin, preferable to zinc oxide. Its sun-screening properties are, however, inferior to those of zinc oxide.

Difficulties sometimes encountered in blending titanium dioxide with other powder constituents may be overcome by using it in conjunction with zinc oxide.

Zinc Oxide

Zinc oxide is the other metallic oxide that is frequently employed in face powders to accentuate their covering power. It is also mildly astringent, mildly antiseptic and has soothing properties. Because of the last property it has been used in the therapy of minor skin irritations. It has been considered to give satisfactory covering power in powder formulations at a level of 15–25 per cent.

The measurement of the covering power of a pigment has been a controversial subject for a long time, since by varying the test conditions one can obtain widely different values.

Grady,[1] who investigated the characteristics of zinc oxide when used in face powders, also calculated the covering power of several face powder ingredients from the refractive indices of the pigments and of the various media in which they might be used for cosmetics. The values obtained are listed in Table 18.1. It will be noted that in the table the covering power of zinc oxide in each medium has been arbitrarily designated as 100; in fact, it decreases progressively from 100 to 37 to 21 as zinc oxide is placed in air, water and petrolatum respectively.

Table 18.1 Calculated Covering Power of Pigments

Pigment	Refractive index	Relative covering power		
		In air (n = 1·00)	In water (n = 1·33)	In petrolatum (n = 1·475)
TiO_2	2·52	166	232	292
Zinc oxide	2·008	100	100	100
Chalk	1·658	55	29	15
Talc	1·589	46	19	6

As well as the medium surrounding the pigment, it is necessary to consider the particle size. A reduction in particle size will obviously allow the material to be spread more thinly and thus give increased physical cover. At the same time, reduction in particle size is, in general, accompanied by increased light scatter, thus increasing the opacity of the powder and hence the optical covering power.

However, there is a limit, and a curve for light transmission for zinc oxide in water, published by Grady (Figure 18.1), shows a sharp increase of transmission (that is, decrease in opacity) below 0·25 μm when the particles have become small in comparison with the wavelength of light.

It should also be borne in mind that the covering power of a face powder will decrease as it absorbs moisture and sebum from the skin. However, under the

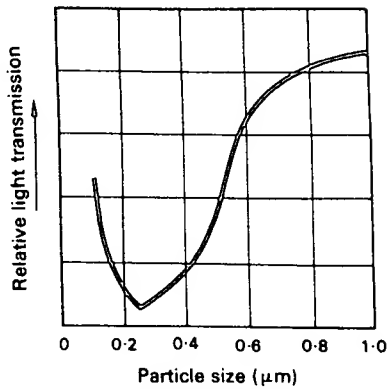

Figure 18.1 Calibration curve relating particle size to relative light transmission[1]

same conditions, pigments with a high refractive index will lose proportionally less opacity than materials of low refractive index, as shown in Table 18.2. This once again emphasizes the desirability of using materials of high refractive index in face powders.

Table 18.2 Relative Covering Power Retained after Wetting Dry Pigment

Pigment	With water (%)	With petrolatum (%)
TiO_2	51	37
Zinc oxide	37	21
Chalk	20	5
Talc	15	3

Grady also drew attention to the sunscreening action of zinc oxide which cuts off the ultraviolet more sharply than any other white pigment used in face powders. He considered, therefore, that zinc oxide and to a lesser degree titanium dioxide should be useful in preventing sunburn. The ultraviolet transmission characteristics of various pigments are listed in Table 18.3.

It is interesting to note that in the experiments carried out by Luckiesh *et al.*[2] on behalf of the US Army Air Force in December 1942 on protective skin coatings for the prevention of sunburn, zinc oxide was found to be of definite value in preventing sunburn whereas titanium dioxide was not found to be a very dependable protective judged on a specimen containing 20 per cent of this substance in petroleum jelly. In addition to titanium dioxide and zinc oxide, some grades of kaolin have a good covering power.

Various published articles have sought to correlate the weight of various face powder constituents with their covering properties or opacities. However, it is

Table 18.3 Ultraviolet Transmission Characteristics of Pigments[1]

Pigment	Per cent transmitted of wavelengths					
	435·8 nm	404·7 nm	365·5 nm	334·2 nm	313·1 nm	302·3 nm
Zinc oxide	46	40	0	0	0	0
TiO_2	35	32	18	6	0·5	0
China clay	63	61	59	57	55	54
Chalk	87	86	84	82	80	79
Talc	90	90	90	89	88	87

not the weight with which the cosmetician is concerned, but the volume, inasmuch as a woman dips her puff into a powder and takes out a volume which depends partially on the adherent properties of the powder, on the size and type of the puff employed and the depth and pressure with which the puff is applied to the face powder container.

To get a very rough idea of the average relative grade of opacity which prevails in cosmetic materials, the opacities of chalk, kaolin, magnesium stearate, rich starch, talc, titanium dioxide, zinc oxide, and zinc stearate were determined by applying these materials by means of a swansdown face powder puff to similar areas of black velvet paper. The whiteness or opacity produced on the smooth black adherent surface was (a) estimated visually and (b) recorded photoelectrically. For the materials employed, the only particle size specification was that they should all pass completely through a 200 mesh sieve. The order of opacity (starting with the least opaque) was found to be as follows:

Talc
Rice starch
Magnesium stearate
Chalk (light, precipitated)
Zinc stearate
Kaolin
Zinc oxide
Titanium dioxide

From what has already been said it will be apparent that to get a true comparison between the relative covering properties of the various face powder constituents it would be necessary to separate similar size particle fractions of each constituent and subject them to exact tests. However, the conditions of such a test, although scientifically more exact, would be so different from the conditions ruling in face powder formulation as to have little actual practical value. The opacities of various finished face powder formulae may be tested approximately by the above method. It should always be remembered that the criterion of effectiveness of a face powder in respect of its water absorption, grease absorption, and covering properties or opacity is judged by the interval elapsing between powdering and repowdering the face; and that a woman judges this by the evidence of shine, which is a complex phenomenon not related to any scientific test and often dependent upon a woman's skin, type of foundation

cream used, and occupation. These facts should be adequately considered by consumer trials, properly carried out and statistically evaluated. Such consumer trials must be carried out scientifically, as ill-conceived trials can be made to prove anything and often prove nothing.

Absorbency

The second important function of face powders is to eliminate shiny skin in certain facial areas by absorbing sebaceous secretions and perspiration. The prime requirement of a material for this purpose is a high absorptive capacity. The components of face powders which confer this property are colloidal kaolin, starch, precipitated chalk and magnesium carbonate.

The water absorbent properties of face powders or face powder constituents may be determined by the method of Hewitt,[3] in which a known weight of the powder is shaken with excess water and filtered under a standard pressure through a Buchner funnel until no more water emerges. The wet powder is then transferred to a weighed, stoppered weighing bottle and the increase in weight determined. Methods involving the addition of water from a burette, until the powder becomes semi-fluid, are open to the objection that different observers do not obtain concordant results and the end point is not easily determined.

Water absorption is by no means the main characteristic required in a powder; it must also be absorbent for grease. If a person's face is inclined to dryness a more greasy foundation is usually employed. A powder which is not grease-absorbent will show a shiny nose or face which will necessitate re-powdering. Constituents of higher opacity such as zinc and titanium oxides tend to mask greasiness, while starch, chalks and kaolin absorb only a certain amount of grease.

Colloidal Kaolin

Kaolin, a hydrated aluminium silicate, is a naturally occurring compound. According to Halpern *et al.*,[4] kaolin is not a primary mineral but is a generic term applied to several hydrated aluminium silicates. Not all aluminium silicates, however, may be called kaolin. On the basis of X-ray and physical studies, Ross and Kerr[5] established that three different groups of clay are classified as kaolin. These clays (kaolinite, nacrite and dickite) have essentially the same formula ($Al_2O_3 \cdot 2SiO_2 \cdot 2H_2O$). Purified grades of kaolin that are light in colour and free from grit and water-soluble impurities should be used for face powders; the most suitable is electrolytically purified kaolin. Ordinary china clay is obtained by elutriation and on microscopic examination mica, quartz and felspar are readily discernible. Pharmaceutical grades of kaolin are obtained by a peptizing process in which the clay is suspended in water containing a suitable electrolyte (for example sodium pyrophosphate) which confers an electrical charge upon the clay and keeps the finer particles in suspension. Removal of the suspension of fine particles, followed by removal of the electric charge (by addition of another electrolyte or by means of an electric field), yields the finest forms of kaolin. One such grade is known as Osmokaolin.

Colloidal kaolin is used in face powders primarily because its high moisture absorption capacity enables it to absorb perspiration. It has also good covering

power, excellent grease-resisting properties and it imparts greater skin adhesion properties to the finished product than does talc. Its relatively high density makes it a useful material for controlling the bulking properties of the powders in which it is used. It also helps to reduce the shine of talc which is present. However, it lacks slip, and is inclined to be somewhat harsh. Its proportion in face powders should therefore not exceed 30 per cent.

Starch and Modified Starches

At one time rice starch was used almost exclusively as the base of face powder formulae on account of its excellent absorptive properties, good covering power and the smoothness it imparted to the skin. The latter property was closely related to its small particle size, the average diameter of rice starch granules being 3–8 μm. However, objections were raised to the use of starch because of its tendency to cake when exposed to a humid atmosphere or in the presence of excessive skin secretions. McDonough[6] asserted that it readily forms a sticky paste when wet, clogging the pores, and that it is an ideal nutrient, when moist, for bacteria. In addition it coats the hair shaft and so accentuates the downy hair, otherwise unnoticeable, on a woman's face. It was also claimed that because of the tendency of starch to favour bacterial growth, it could give rise to skin irritation when in contact with the skin for any length of time. These assertions led eventually to the replacement of rice starch by talc as the powder base in face powders. However, it must be said that when any degree of bloom is required, there are few materials which can surpass starch.

Decomposition can be reduced in many cases by the addition of perfume; mention of clogged pores refers not to pores but to the openings of the hair follicles. (Pore openings are invisible by ordinary inspection.) There is no proof that starch can cause clogging of such openings.

Special grades of treated starch which will not swell up or agglutinate in the presence of moisture have been developed for the cosmetics industry. For example, ANM starch powders (Neckar-Chemie, GmbH) are starch ethers which are produced by reacting the hydroxyl groups of the starch molecule with tetramethylolacetylenediurea. These materials are claimed to have a good slip, good adhesive properties and covering power, and a high absorptive capacity for both water and oil. They are chemically inert and are also claimed to have some bactericidal properties by virtue of their small formaldehyde content. The ANM Rice 'K' grade was claimed, unlike untreated rice starch, not to swell in the presence of moisture or perspiration, and not to give rise to enlarged pores and bacterial decomposition. As in the case of untreated rich starch, it is said to confer a peach-like bloom to the skin, and to be superior to talc in terms of covering power.

Microcrystalline Cellulose (Avicel)

Avicel is a microcrystalline cellulose from the FMC Corporation.

It is interesting to note in this connection that in 1966 a powder was launched which, unlike conventional face powders consisting of talc or starch, was claimed to contain microporous cellulose derived from the centre of the corn cob, with an oil absorption rate many times higher than other powders.

Precipitated Calcium Carbonate

Precipitated chalk is yet another material that has been used in face powders because of its excellent absorption characteristics. Like kaolin it is also used to remove some of the inherent shine of talc. It has, however, a deleterious effect on the slip of the product and tends to impart an undesirable dry feel. Consequently (unless it is one of the special grades available) it should not be used in face powder formulations in amounts greater than 15 per cent.

The special grades of precipitated chalk are exceptionally fine and accurately balanced to prevent harshness. They possess good absorption and grease-resisting properties and are available in different densities, depending on the purpose intended. When such grades are used, it is possible to use considerably greater amounts of precipitated chalk than specified above. A specially treated grade of precipitated chalk is also available which is claimed to be unaffected in terms of its absorptive power for oils and grease, which does not dry the skin, and which is claimed to be particularly adhesive. These materials are guaranteed to conform to the USP specification for lead, arsenic, etc.

Magnesium Carbonate

Magnesium carbonate is a highly absorbent constituent of face powder formulations. Its absorbent power is about three times as great as that of precipitated chalk and its tendency to dry the skin correspondingly greater. Magnesium carbonate confers fluffiness to face powders and helps to prevent 'balling'. Light magnesium carbonate is the preferred substance for incorporating and maturing the selected perfume. It is subsequently blended with the bulk of the powder; 5 per cent magnesium carbonate is ample for this purpose.

Plastics

Powder bases made from plastics have been developed for use on the skin. These powders are available both in the form of solid spherical particles and in the form of a crushed foam. An example of the latter is 'Oracid'—a rigid urea-formaldehyde foam. Tables 18.4 and 18.5[7] show oil absorption and water

Table 18.4 Oil Absorption Capacities of Powder Bases[7]

Substance	Oil take-up (ml per g of substance)	Saturation time (min)
Oracid (urea-formaldehyde foam)	11·11	15
Aerosil	6·00	15
Magnesium carbonate	5·40	15
Magnesium oxide	3·30	15
Kieselguhr	2·80	15
Kaolin	2·70	15
Talc	2·50	15
Rice starch	2·10	15
Zinc stearate	0·40	15

Table 18.5 Water Absorption Capacities of Powder Bases[7]

Substance	Water take-up (ml per g of substance)	Saturation time (min)
Oracid (urea-formaldehyde foam)	16·60	30
Aerosil	8·70	45
Magnesium carbonate	4·03	28
Kieselguhr	3·20	12
Magnesium oxide	2·60	20
Titanium dioxide	2·30	30
Kaolin	1·50	5
Talc	1·40	10
Zinc oxide	1·10	18
Rice starch	0·75	15
Zinc stearate	0·05	120

absorption capacities of various powder bases, including Oracid, in terms of ml absorbed and the time taken for the saturation value to be reached.

Use of finely divided, highly crystalline, high density polyethylene as a substitute for talc in cosmetic powders has been described in a US patent.[8] Preparations containing polyethylene are claimed to be non-irritant and to have good adhesion, covering power and absorbency. The average particle size of the polyethylene used in cosmetic powders should preferably be not larger than 44 μm. For coloured compositions, for example powder rouge, the dye should preferably be incorporated in the molten polymer, rather than mixed with dry powder constituents.

Cosmetic powder preparations in solid, liquid or slurry form based on finely divided polymeric polyesters are claimed in a British patent.[9] These preparations are claimed to spread easily and to adhere tenaciously to the skin, giving a velvety matt finish. The polymers employed are high-molecular-weight polymeric linear polyesters such polyethylene terephthalate and isophthalates, or a copolymer of these two monomers, with a preferable average particle size of 1–10 μm. Cosmetic powder preparations based on mixtures of these polymeric particles preferably also contain one or more of the usual additives of cosmetic powders such as talc, kaolin, zinc oxide and metallic soaps to improve spreading characteristics, slip, adhesion and absorptive capacity for oily secretions and perspiration.

Polystyrene microspheres are a further example of polymeric materials developed for use in cosmetic powders.[10]

Slip

Slip is the quality of easy spreading and application of powder to produce a characteristic smooth feeling on the skin.

Slip is mainly imparted by talc and also by metallic soaps such as zinc stearate and, to a lesser extent, starch.

Talc

Talc is a hydrated magnesium silicate to which the formula of $3MgO{\cdot}4SiO_2{\cdot}H_2O$ has been assigned. In fact, the Mg/Si ratio appears to vary.

Talc may be obtained from Italy, France, Norway, India, Spain, USA, Australia, China, Egypt and Japan. Of these, the Italian, French, American, Australian and some Indian and Chinese grades can be used for face powders and compact powders. The grinding of raw talc is an important parameter in determining its suitability for make-up products. Talc must be very white and bright to allow products to cover the wide range demanded by the modern consumer and this can only be achieved by having the correct grinding process. Products can always be 'dulled off' with the use of colours but, to produce a 'bright' product, the talc must be bright in the first place. This phenomenon cannot be introduced by the use of other materials. One may even have to use two different types of talc to cover all products, for example one grade for make-up products and another cheaper grade for talcum powders, etc. Whatever the source of the talc it must be free from asbestos or 'amphibole material' and care must be taken with lower grade materials, since talc from certain countries may contain tetanus spores. In such cases it is essential that the talc is adequately sterilized (see also Chapter 8).

Talc is the major component of face powders, and in high class products it may be used in amounts of up to 70 per cent or more. Its main function in such powders is to impart to them slip and good adhesion. However, the covering power and the moisture absorbing capacity of talc are low, and it must therefore be combined with other powders to modify these deficiencies. Apart from its use in face powders, talc is, of course, used in talcum powders, baby powders and antiperspirant sticks, all of which are discussed under their appropriate headings (Chapters 7, 8 and 10).

The most suitable physical form of talc for use in cosmetics is the foliated variety, the flat platelets of which slide readily over each other, thus accounting for the high slip characteristics of the product.

In the USA, the standards of the Cosmetic, Toiletry and Fragrance Association stipulate that talc should be free from impurities such as carbonates and water-soluble iron and be neutral to litmus paper, so as to prevent any deterioration of colour and perfume in the finished product. In order to ensure the application of a smooth and even film, the talc used should also be free of any gritty particles and shiny specks of mica, and the bulk of it should pass through a standard 200 mesh sieve. It should also be free of asbestos, this requirement being emphasized in the USA by the OSHA regulations concerning asbestos-containing materials; a review of properties and specifications is given by Grexa and Parmentier.[11]

Adhesion

Adhesion is another important property of face powder constituents, determining how well the powder will cling to the face.

The property of adhesion is imparted to face powders by the inclusion of talc and some water-insoluble metallic soaps of stearic acid, such as zinc and magnesium stearates. The latter are used in face powders in amounts ranging

between 3 and 10 per cent. In addition to increasing the adhesion of the powder to the skin, they also render the ultimate product soft and fluffy and furthermore impart to powders some water-repellent characteristics.

The adhesion of powders to the skin can also be improved by the incorporation of certain emollients such as cetyl or stearyl alcohols and glyceryl monostearate, usually in amounts varying between 0·5 and 1·5 per cent.

Various proprietary preparations have been marketed from time to time, having as their object the improvement of the adhesiveness of face powders. One British patent[12] describes the use of the zinc or magnesium salts of fatty acids containing an uneven number of carbon atoms, for example undecylic acid, such a base being employed in a proportion of 5–10 per cent in the finished powder. Many manufacturers prefer to correct any lack of adhesiveness in their product either by increasing the amount of zinc or magnesium stearates incorporated or by including in the powder mixture 2 per cent of petroleum jelly, mineral oil or cetyl alcohol. Further variations can be made using encapsulated mineral oil, especially when one is trying to produce a very light fluffy powder and yet achieve good adhesion.

Among other materials which have been suggested, mention may be made of powdered kapok proposed by Varma[13] as a potential face powder ingredient. Powder bases made from plastics, which were referred to earlier, have also been claimed to give improved adhesion.

Powdered Silica and Silicates

Very finely divided pure silica has been introduced for cosmetic purposes, for example Neosyl (Crosfield) and Aerosil (Degussa). It is claimed that the use of this substance obviates the need for zinc and magnesium stearates. The addition of 10 per cent to an ordinary powder mix exerts a marked effect in increasing its fluffiness. Up to 20 per cent may be used in a face powder or 30 per cent or more in talcum and baby powders. The incorporation of a small amount of such an ultrafine silica is very efficient as an anticaking agent in body powders.

In addition to silica, a number of ultrafine synthetic silicates which have extremely high oil and water absorption properties may also be incorporated into face powders.

Bloom

The materials chiefly used to impart bloom, the requirement for which may vary according to fashion, are chalk, rice starch and prepared starch. These have been described above.

Powdered Silk

A raw material for face powders (and other cosmetic preparations) which, apart from any unique or desirable properties it may have, will provide opportunities for the advertising agencies to produce rapturous copy writing, is powdered silk.

A British patent[14] describes a process for its preparation. Two further patents[15,16] have been taken out dealing respectively with a technique for pulverizing silk for producing silk powder and a method for breaking down silk by boiling successively in sulphuric and boric acids.

Powdered silk was also discussed in *Schimmel Briefs*,[17] where it was pointed out that raw silk consists of fibroin, a protein fibre, covered with a coating of a gummy material called sericin. The latter consists mainly of albuminoid substances with small amounts of fatty acids, resin and colouring matter. The silk is, therefore, first degummed by the conventional processes used in the textile industry, then treated with acid or alkali in order to bring about a partial hydrolysis of the protein molecules. At an appropriate stage it is washed and dried, and finally reduced to an impalpable powder by grinding.

It has been claimed[18] that the physical characteristics of silk powder make it well suited to serve as an ingredient of face powders, that it spreads easily and adheres tenaciously to the skin, producing a velvet matt finish, and that it possesses a very high absorbent power in that it will absorb as much as three times its volume of water and still retain the appearance of a powder. The addition of large amounts of such materials as kaolin or chalk is not advised, as it is claimed that they tend to make the final product too dense and compact.

Colour

Inorganic and organic pigments and organic lakes have all been used to confer colour to face powders. Water-soluble or oil-soluble dyestuffs should be avoided because of the danger of colour bleeding after application due to solubilization by sweat and lipid secretions. Inorganic pigments include natural and synthetic iron oxides which give yellows, reds, browns and black; ultramarines which give green and blue, and chrome hydrate and chrome oxide which give green.

Within the EEC all colours used in cosmetic products, together with their purity limits, are governed by the Cosmetics Directive of 1976.[19] In the USA the Food and Drug Administration controls the use of colours in cosmetics, but specifies purity limits only for the organic colours. However, it is recognized that inorganic pigments should be produced to a 'certifiable standard' which usually refers to heavy metal content and the Cosmetic, Toiletries and Fragrance Association have issued standards for these materials, for example iron oxides, that are in line with the Food and Drug Administration standards.

There is a considerable activity on the part of the Food and Drug Administration in the USA in regulating the materials to be used in, *inter alia*, toilet preparations. This involves not only the well known ranges of FD&C, D&C, and D&C (Ext.) colours, but also many inorganic materials both coloured and uncoloured which have been mentioned above either as additives (colours) or main materials. Present use is permitted pending the consideration by the FDA of applications for materials to be specifically on the permitted list.

Because of different proprietary names and numbers for various colouring matters, local regulations—as for example the use only of colouring matters certified by the FDA in the USA—and different opinions among firms themselves as to what particular combination of colours gives their 'particular' rachel, peach, tango, etc., no attempt has been made to list the multifarious colouring matters available. Useful information may be obtained by consulting the US Colour Regulations and the Colour Index[20] (see also Harry's *Cosmetic Materials*,[21] wherein ninety pages are devoted to listing the properties of these colouring matters). From a description of their solubilities, etc., it will be

possible to rule out a number of these dyes; of the remainder belonging to the colour classification desired, a number will be found to be obtainable of similar composition in other countries[22] but without, in every case, the guarantee of various metallic and other impurity limits. The task of the formulator will often be simplified by consulting dyestuff manufacturers who will readily advise on suitable colouring matters, oxides and earths and give advice concerning proportions for various colour matches which may be required. Suitable blends of colours are readily available conforming to local regulations, and it is well worth while to evaluate them in one's own formulations before spending too much time on colour blending. The colouring of face powders has been discussed by Anstead.[23]

The choice of colour is usually a matter of taste. At one time it was considered, that 'naturelle' (clear pink) shades were suitable for blondes, and 'rachel' (more cream–yellow) shades for brunettes. Later, perhaps because of more outdoor exposure, it was realized that the natural skin colour tends more to a cream colour, and that the old 'naturelle' now suits only a few complexions which by reason of their transparent skin tend naturally toward blue. Conversely, florid complexions may be toned down by pale bluish green powders. The majority of the present-day range of colours are based on a cream–yellow–brown range.

As well as the actual complexion itself, varying colours of hair and dress all affect the apparent tint, which probably accounts for the multitude of colours in demand (see also Chapter 20).

It is advisable to keep colour formulations as simple as possible so that matching with fresh batches of raw material is made easier. The colour effect produced by a powder applied to the skin will depend *inter alia* upon the opacity of both tinted and white pigments, their particle size, the degree of dispersion, the thickness of the applied film and the colour of the skin.

The colour of the thin film of pigment (the undertone) may be different from the colour effect given by the powder viewed in bulk (the mass tone). It is thus important that the formulator assesses the performance of the product applied to the skin.[24]

Perfume

The importance of the perfume on the sales appeal of the product cannot be over-emphasized. Usually the powders are perfumed very lightly. The odour of the face powder must be fragrant and pleasant, and a preference is shown today for either a flowery fragrance or that of a synthetic bouquet. Unless the manufacturer has had wide experience of perfume manufacture he will be well advised to purchase the perfume from a reputable perfume manufacturer.

The compatibility of perfume with other constituents of the product must be carefully checked. Talc, for example, usually contains a little free lime, magnesia or iron which may adversely affect the perfume depending on the amount of these substances present. The perfume may also be affected by precipitated chalk, by kaolin, magnesium carbonate or a metal stearate, if these contain impurities, or indeed by some of the pigments used in colouring the powders. Finally, it should be remembered that the perfume note in a powder will be

different from that, for example, in an alcoholic solution, particularly in the case of floral bouquets, and any tests on perfume acceptance must be carried out on the final product.

Formulation

The chemist familiar with the properties and functions of the various powder constituents and with the sources of supply will have no difficulties in formulating a satisfactory product. He should, however, be given details of the type of market for which the product is intended, the advertising story to be used and properties to be highlighted. He will then be able to judge what proportions of which constituents to use, and which materials to avoid in order to produce a suitable formula. Thus, for powders with a good covering power, he will use a higher proportion of either zinc oxide or titanium dioxide; for increased absorbency, the proportion of magnesium carbonate may well be raised at the expense of talc, and where a powder with good adhesion is required the amount of zinc or magnesium stearate may have to be increased.

Multifarious variations in formulae could be listed, many of which, under laboratory conditions, show slight differences in respect to opacity, slip, absorbency, water-resistance and grease-resistance, etc., but experience shows that many of these variations cannot be detected by the average woman under normal conditions of use. The following formulae exemplify various types of face powder, the variations in which are sufficient to be detectable.

The powder given in example 1 is very transparent, that is it is a 'light' powder, and is favoured by persons who wish to impart some colour and bloom to the face without appearing to be 'made up'. The starch may be replaced if desired with precipitated chalk.

	(1) *per cent*
Talc	80·0
Zinc oxide	5·0
Zinc stearate	5·0
Rice starch	10·0
Perfume, colour	*q.s.*

Example 2 has high opacity and gives a very definite opaque matt finish which tends to hide minor skin defects. It is more popular with certain people who like to have a definite powdered appearance without being over-powdered.

	(2) *per cent*
Talc	30·0
Zinc oxide	24·0
Zinc stearate	6·0
Precipitated chalk	40·0
Perfume, colour	*q.s.*

In between these two types of powder there are a number of popular variations such as the following:

	(3) *per cent*
Talc	65·0
Precipitated chalk	10·0
Zinc oxide	20·0
Zinc stearate	5·0
Perfume, colour	*q.s.*

	(4) *per cent*
Talc	60·0
Kaolin	20·0
Zinc oxide	15·0
Zinc stearate	5·0
Perfume, colour	*q.s.*

As previously stated, both starch and precipitated chalk tend to impart bloom; example 5 is a powder of medium weight, that is medium opacity or coverage and bloom.

	(5) *per cent*
Talc	50·0
Rice starch	15·0
Precipitated chalk	15·0
Zinc oxide	15·0
Zinc stearate	5·0

If it is desired to obtain maximum coverage and still maintain a high talc content, this may be achieved by replacing the zinc oxide in any of these formulae by about one-quarter of its weight of titanium dioxide.

The following formula is prepared from precipitated chalk and a high proportion of zinc stearate is incorporated. To provide some grease-resistance, kaolin and titanium dioxide are employed.

	(6) *per cent*
Waterproof chalk base	50·0
Zinc or magnesium stearate	10·0
Kaolin	20·0
Titanium dioxide	6·0
Talc	14·0
Perfume, colour	*q.s.*

Jannaway[25] states that the following formula gives a good medium powder, characterized by excellent slip, absorbency, adequate coverage, good velvety feel and adherence—and an indefinable improvement in mattness, etc., which is

attributed to the rice starch:

	(7) *per cent*
Zinc oxide	16·0
Talc	37·0
Zinc stearate	5·0
Precipitated chalk (light)	18·0
Rice starch	8·0
Kaolin (best cosmetic grade)	16·0

Winter[26] has described a special kind of 'fatty powder' which he states is much favoured by persons afflicted with a rough or dry skin:

	(8) *parts*
Vaseline	50
White beeswax	40
Petroleum jelly	40
Stearin	20
Glyceryl monostearate	75

Procedure: Melt the above fatty materials together and add, while stirring constantly, 500 parts of hot water. Continue to stir until the emulsion has formed, then add 1000 parts of talc. Knead, allow to dry, rub to powder, pass through a sieve and perfume.

Other formulations are given by Keithler[27] and Hilfer.[28]

The modern trend with face powder is to apply it over foundation to achieve special effects, for example, matt or shimmer. The following complete formula illustrates a light shimmering effect:

	(9) *per cent*
Talc	77·00
Zinc stearate	5·00
Zinc oxide	2·00
Kaolin	5·00
Mica	10·00
Red iron oxide	0·36
Yellow iron oxide	0·36
Black iron oxide	0·03
Perfume	0·25

Manufacture

Mixing of the ingredients in face powders is usually carried out in a horizontal mixer with a screw agitator. If lakes are used they may be mixed with a small quantity of one of the constituents, chalk, zinc oxide or talc, and the colour concentrate so formed mixed with the main bulk. If water-soluble or alcohol-soluble dyes must be used they are best sprayed on to the mix or alternatively on

to one of the constituents which possesses good absorbency such as chalk, kaolin or magnesium carbonate, this being then dried and mixed into the main bulk.

Machines are available which mix, sift and spray the perfume automatically. One method would be to add the perfume by a meter pump feeding a long tube with a multitude of small holes fitted along the top of the blender (for example, on to magnesium carbonate or chalk in the ribbon blender) before mixing with the remainder of the powder.

The use of water-soluble or oil-soluble colours should be avoided in a face powder since they lead to streaking, darkening and staining of the skin when applied over ordinary make-up. Chilson[28] has drawn attention to the pebble mill method of mixing which obviates the making of a colour base. All the ingredients, including the colour and perfume, are milled together in a pebble mill for six hours, discharged and then sifted. He states that such a mill delivers an excellent product and is widely employed in preference to mixers. This method, however, is too slow to be recommended for large-scale production. Micropulverizers are being increasingly employed since the material obtained is finely ground and uniformly mixed and only a rough pre-mixing is required. Various other pulverizers such as disintegrators, hammer mills, attrition mills, etc., may also be used.

Pin-disc mills give good results, especially in respect of colour dispersion, provided that the material is first given a rough pre-mix. Such mills are often applied in conjunction with a turbine sifter.

The Air Spun Process employed by Coty Inc. is described briefly by deNavarre[30] as follows:

> . . . Purified and cold air, under great pressure (100 psi; 700 kPa) is permitted to rush in a continuous stream into a closed drum-shaped chamber. This chamber or mill is called a micronizer because it reduces particles to micron (μm) size. The speed of the air stream, the manner in which it is directed and the shape of the chamber itself, cause air to revolve about this chamber at a rate somewhat in excess of 1000 mph. In this super cyclone all the ingredients are hurled against each other until they reduce themselves to the desired size and fluffiness. When this is attained such particles are emitted through a central exit while the heavier particles are forced to remain. It is claimed that the particle size was selected after numerous experiments had shown it to be the best for the appearance, effect and adhesiveness of a face powder.

Apart from this process, various physical methods exist for preparing powders of a desired particle size range. These depend upon elutriation by means of air or water. Control of such separated fractions may be carried out by microscopic examination of the fractions, but this method involves the visual or photomicrographic inspection of a very large number of fields in the microscope and is tedious. Various sedimentation tests, some based upon passage of a beam of light through the sedimentation column into a photoelectric cell, have also been suggested. One of the simplest methods for the cosmetician is that based upon the principles of Stokes's Law, described by Hinkley.[31] A useful variation is the method of Andreason in which volumes of the suspension, after definite times of settling (calculated from Stokes's Law) are pipetted into a tared dish, evaporated to dryness and weighed. Various air permeability methods are also widely used.

The most modern method of particle size analysis applicable to cosmetic powders entails the use of a Coulter Counter. A paper dealing with the subject was presented by Wood and Lines.[32]

Packaging is usually carried out by automatic vacuum filling devices, which minimize dusting.

In choosing powder boxes, care should be taken to see that these are prepared with an odourless glue, otherwise the fragrance of the powder will be ruined in storage.

COMPACT POWDER

Because they are convenient to use, compact powders enjoy wide popularity. They are nowadays prepared by either a damp or a dry compression process. The moulding process used originally, which entailed the use of plaster of Paris, has fallen into disuse.

In the damp process, the powder, intimately mixed with a suitable binding agent, is milled to the requisite plasticity, compressed into suitable containers, usually metal godets, and dried for the requisite period in a current of warm air. In the dry process the mass is subjected to compression without being wetted to any appreciable extent. This process, although difficult to achieve satisfactorily at first, is probably the best to use for manufacturing compacts on a large scale, because it can be rigidly adhered to once the mix and suitable conditions have been determined. Presses available for the manufacture of compact powders may be of the hydraulic or reciprocating mechanical type, varying in size, operating pressures and output. They range from foot operated presses producing one cake at a time, to fully automatic presses which may produce up to 60 units per minute.

The requirement of good covering power, adhesion and uniformity in compositions mentioned in respect of conventional face powders also applies to compact powders. The latter should, in addition, be easy to remove from the cake for application by means of a powder puff, without crumbling or breaking during handling; this requirement is met by conferring adequate binding properties to the powder mixture to be compressed. Furthermore, the powders used for compacts should be free-flowing so that they do not adhere to punches or dies during compression; otherwise, air pockets will be formed which will result in an uneven compression and cause the cakes to break. From this it can be seen that one of the main aims during manufacture of compact powders is to ensure that the compressed cakes are of uniform density.

The main difference between loose powders and compact powders lies in their binding properties. If these are inadequate, the compressed cakes are liable to crumble easily following compression. If they are excessive, the cake will form lumps and go greasy on application. Thus, satisfactory binding properties are essential for trouble-free compression and the production of good quality cakes over long manufacturing periods.

The actual pressing process can also affect the shade of the product so quality control can be a problem. In fact, if large volumes are anticipated it is always best to conduct an extended manufacturing trial rather than go straight from the laboratory bench into full-scale production.

The composition of compact powders is generally very similar to that of loose powders. The differences which exist arise from the need to meet the requirement of greater cohesion and are largely evident in terms of percentages of some of the components present. In compact powders, colloidal kaolin, zinc oxide and metallic stearates are usually present at a higher level than in loose face powders, and starch is sometimes incorporated to facilitate compression. If the powders are not sufficiently binding they will require the addition of a binding agent to improve their cohesion so that on compression a firm cake is produced. Water-soluble and water-insoluble binding agents may be used. The former are natural and synthetic gums which are used in amounts ranging from 0·1 per cent to about 3 per cent by weight of the product, and are usually mixed with component powders in the form of a 5–10 per cent aqueous solution. A very much favoured binding agent for this purpose is low-viscosity carboxymethylcellulose. A small amount of a humectant is usually added to the solutions. If a water-insoluble binding agent is employed, for example glyceryl monostearate, cetyl or stearyl alcohols, isopropyl esters of fatty acids, lanolin and its derivatives or ozokerite, paraffin wax and microcrystalline waxes, it is preferable to use it in the form of an oil-in-water emulsion so that it is uniformly distributed throughout the product.

In the dry compacting process, it is usual to employ zinc or magnesium stearates at a level of 5–15 per cent by weight, as well as a lubricant such as mineral oil in similar proportions.

Considerable changes have taken place in formulation during the last forty years or so; thus in 1932 Winter[33] recommended an ammonia–stearin–starch compound containing white petrolatum, ammonia, starch and stearin (example 10) for the manufacture of compact powder and rouge.

	(10)
Stearin	100 g
White petrolatum	20 g
Ammonium hydroxide solution, 0·97 s.g.	50 cm^3
Rice or maize starch	250 g

Procedure: Melt the stearin and the petrolatum together. Add the ammonium hydroxide solution and stir thoroughly while hot. Add the starch to the warm mixture with vigorous stirring (during the addition, thick lumps will form in the starch powder; with vigorous stirring and pressing, these break down and mix with the starch). Rub the resulting crumbly mass in a mortar and then pass it through a 70–80 mesh sieve. Cool well before sifting.

This compound is added, in a proportion of 13–15 per cent, to the powder base together with the colouring matter, and the mixture is subjected to pressure. It is stated that such pressing should not be carried out suddenly but by gradually increasing the pressure. Experiments have fully confirmed this opinion. Unless a little time is given for the air to escape gradually, it becomes entrapped in the compact with disastrous results.

As mentioned previously, rice starch has been used in compact powder manufacture to facilitate compression of the powders. There has, however, been some controversy regarding the maximum permissible proportion of starch in a compact. On one hand, views were expressed to the effect that the starch content should be low, otherwise there is a tendency to produce hard cakes and to make the removal of the powder, when the puff is applied, more difficult.[34] One formula quoted included only 2·5 per cent of rice starch.[35] Winter, on the other hand, considered that starch acts as a good binding agent and recommended a base containing about 13 per cent of starch.[33] In yet another article, up to 20 per cent of starch was regarded as helpful in binding a compact.[36]

Winter suggested the powder base mixture given in example 11, to which may be added 13–15 per cent of stearin-starch and the required colouring matters. Water is added to produce a dough-like paste which is dried, ground and passed through a 120 mesh sieve and the mass compressed into a suitable metal case or godet.

	(11) *per cent*
Talc	26·7
Kaolin	56·7
Zinc oxide	3·3
Rice starch	13·3

Modern manufacturing procedures and compositions vary appreciably from those just described. In the case of the damp process, any colours to be used are first ground with the powder constituents, and the resulting mixture is passed through a sieve. The powder is then moistened with the binder solution or emulsion and perfume is incorporated. After a thorough mixing, the blend is sieved once more, for example through a 60 mesh sieve. The produce is then dried at room temperature or in warm air, provided that the temperature used does not exceed that at which the perfume will volatilize. The product is then compressed and placed in suitable containers.

Example 12 gives a formula to which the damp compression process is applicable.

	(12) *per cent*
Kaolin	20·0
Zinc oxide	15·0
Precipitated chalk	25·0
Talc	32·0
Compact binder (e.g. soap)	8·0
Perfume, colour	*q.s.*

The second of the two modern compacting processes, that is the dry compression method, is particularly suitable for mass production, but necessitates the use of higher pressures than are employed in the damp compression process. The manufacture of a compressed face powder cake by the dry compression process has been described in some detail in a US patent[37]. In an

embodiment example of this patent the following composition and procedure were given:

	(13) *per cent*
Talcum	61·25
Sodium lauryl sulphate	0·75
Titanium dioxide	7·50
Zinc stearate	11·25
Inorganic pigments	1·00
Mineral oil	4·50
Spermaceti	3·00
Cetyl alcohol	1·50
Lanolin	1·00
Glycerin	7·50
Hexachlorophene	0·25
Alkyldimethylbenzyl ammonium chloride—50%	0·20
Methyl-*p*-hydroxybenzoate	0·09
Propyl-*p*-hydroxybenzoate	0·09
Perfume	0·12

Procedure: Talc, sodium lauryl sulphate, titanium dioxide, zinc stearate and inorganic pigments are first mixed together in a ribbon mixer for about an hour. Next, hexachlorophene, quaternary ammonium base and preservative, thoroughly premixed, are added to the mixer and the batch is mixed for about two hours, before passing through a micro-pulverizer using a no. 0·013 screen. The temperature of the material should not be allowed to rise more than 10°C above room temperature during this operation. After cooling, the powder blend is repassed through the micro-pulverizer. The mineral oil, spermaceti, lanolin and glycerin, mixed with heating until liquid, are then sprayed into the dry batch which is mixed in the ribbon mixer for a further half hour. The batch is passed through a comminuter and once again through a pulverizer, using a 3/16 in screen and taking the same precautions about temperature as before. When cool, the powder is passed through the micro-pulverizer using a no. 0·027 screen, and finally, having been cooled once more, is passed through a 40 mesh screen, ensuring that no heat is generated during this final screening. The resulting material is filled into containers and pressure is applied, for example 40–50 psi (300 kPa), to convert the powder into cake. It is usually advisable to keep the powders for several days in a suitably humid atmosphere before pressing, to facilitate the escape of any trapped air, and to ensure that the powder blend will not be too dry when compressed. During the dry compression process, it is usual to apply a small pressure initially to squeeze out the air, and thus avoid the formation of air pockets in the powder cakes. Pressure is then gradually increased up to 150 psi or even more (1000+kPa) before the die is removed from the surface of the cake. It is possible, however, with careful formulation and preparation of the powder to press the cakes with immediate pressures of up to 600 psi (4 MPa) and outputs approaching two thousand units per hour.

CAKE MAKE-UP

The modern cake make-up originates from theatrical grease-paint and has acquired popularity because of its ease of application and stability and also

because more product can be applied to the face and thus deeper shades and effects can be achieved. As in the case of compact powders, the cake make-up is also made from talc, kaolin, zinc oxide and precipitated chalk, but it contains, additionally, inorganic pigments such as titanium dioxide and iron oxides. Humectants such as sorbitol or propylene glycol may also be incorporated together with other additives such as sorbitan sesquioleate, lanolin or mineral oil and perfume. Humectants and other liquid constituents are usually combined and sprayed on to the powder constituents while these are mixed in the ribbon mixer. The resulting blend is granulated and finally compressed.

Patents[38,39] granted in the 1930s claimed a product in cake form which, when applied to the face using a damp sponge, dried to form a coherent water-repellent film of powder. The advantage of this product is that no foundation cream is required and make-up can be retouched very quickly and conveniently.

A patent by Max Factor[40] describes a dry cake-form make-up which can be applied with a moistened pad or sponge. The cake contains oily and waxy ingredients (0·8–24 per cent), a water-soluble dispersing agent (1–13 per cent) and fillers (35–80 per cent) and pigments (12–50 per cent) whose particles are coated with the oils and waxes to make them water-repellent. The make-up is prepared by adding the fillers (talc, chalk) and pigments (zinc, titanium and ferric oxides) to the oils and waxes dispersed in water, drying the mixture so formed, pulverizing the product, and compressing it into cake form.

Products made to this style of formula can be prepared without drying by using a much higher ratio of powder to emulsion, for example approximately 12 to 1, and mixing with a Beken Planetex or Duplex mixer. The mixing operation takes between 30 and 60 minutes and the mix is compacted after granulating through a fine screen.

The following formulae can be made in this fashion:

		(14) *parts*
Powder base (perfumed)		100
Emulsion:		
Stearic acid	34·5	8·5
Mineral oil	21·5	
Triethanolamine	10·5	
Water	33·5	

For deep shades with good coverage, zinc oxide should be replaced by titanium dioxide (this also facilitates better pressing characteristics):

Colour mix:	(15) *per cent*
Talc	89·75
Titanium dioxide	9·00
Yellow iron oxide	0·75
Red iron oxide	0·40
Black iron oxide	0·10

Base:	*per cent*
Stearic acid	15·0
Acetylated lanolin	3·0
Stearyl alcohol	3·0
Glyceryl monostearate (self-emulsifying)	2·2
Sulphonated castor oil	1·2
Triethanolamine	3·0
Mineral oil	35·0
Polyethylene glycol	10·0
Water	27·6
Completion ratio:	
Base	20·0
Colour mix	79·8
Perfume	0·2

Pressing of this product can be very rapid as for compact powders, although it is important to check that there is consistent dispersion of the base in the colour mix throughout long manufacturing runs.

A prototype cake make-up formula suggested in a cosmetic formulary of Atlas Industries[41] had the composition given in example 16.

	(16)
Pigment blend:	*per cent*
Talc	60·0
Kaolin	20·0
Zinc oxide	10·0
Titanium dioxide	5·0
Calcium carbonate, light	5·0
Iron oxide colours	*q.s.*
Completed formula:	
Pigment blend	81·4
Arlex (sorbitol)	4·1
Propylene glycol	2·4
Arlacel C (sorbitan sesquioleate)	9·7
Mineral oil or lanolin	2·4
Perfume, preservative	*q.s.*

Procedure: Mix the Arlex (sorbitol) with the propylene glycol and preservative and spray this mixture into the powder while it is being mixed in a dough mixer. Mix the Arlex C and mineral oil. If lanolin is used, melt the lanolin with the Arlacel C. Add the perfume and spray on to the powdered mass which is agitated in the dough mixer. Transfer to a Fitzpatrick tablet granulator or an equivalent machine. After granulation, the mass is ready for performing and compression. The same procedure is employed as in the case of compact powders, that is the initial application of a relatively light pressure (about 25–50 psi; 250 kPa) to remove air, followed by the application of a higher pressure of 100–150 psi or more (1000 + kPa).

Application of Cake Make-up

Maurice Seiderman, a pioneer of make-up in the motion picture industry, recommended the application of cake make-up in the following manner: 'To apply cake make-up correctly, wet and squeeze out a sponge and rub it lightly over the face. Smooth the cake make-up on the face and before it dries blend in the rouge. Carefully squeeze all water out of the sponge and rub it lightly over the face until the make-up is dry.' Macias-Sarria[42] adds that people who do not like a heavy make-up should blot off the excess of water with a dry towel or facial tissue.

It is claimed that cake make-up is satisfactory for the younger woman; in the case of persons in the later thirties, and even younger persons who suffer from dry skin, it is found to be rather drying. To cater for this market, to coincide with the general trend towards more greasy make-up as exemplified by many foundation creams and possibly also with a view to cashing in on the flat type of pack in which cake make-up is packed, a greasy type of compact containing pigments of high covering power in a waxy base has been marketed.

Such products appear to be poured instead of being compressed in the usual manner. Wetting agents may be incorporated so that these products may be removed with a damp sponge; alternatively, silicone oils may be used to improve the spreading characteristics and make the product suitable for finger-tip application.

MAKE-UP CREAM

Foundation make-up preparations in cream form are essentially suspensions of pigments in an emulsified lotion. The addition of the pigment is usually made at about 50°–55°C as the emulsion is slowly cooled with agitation. Janistyn quoted the following formula for a cream make-up.[43]

	(17)
	parts
Glycerol mono- and distearate (pure)	2·0
PEG 400 monostearate	1·0
Stearic acid	11·5
Cetyl alcohol	0·5
Isopropyl myristate or palmitate	2·0
Propylene glycol	12·0
Sorbitol syrup	2·5
Preservative	0·1
Titanium dioxide	2·2
Talc	8·0
Colour pigments	1·0
Water	57·4

The suspension is usually homogenized and milled.

LIQUID POWDER

So-called 'liquid powders' have sometimes been used as a base for ordinary powder or to replace such powder for evening wear, dances or similar occasions. They have also included a theatrical product, 'wet white', which was used for

whitening the neck and arms. Its basic components were zinc oxide and bismuth oxychloride, subnitrate and carbonate incorporated into a liquid consisting of a mixture of glycerin and water in varying proportions. Glycerin was employed in amounts of up to 30 per cent and the water was often replaced by triple rose water or other fragrant waters; starch was also used sometimes to suspend heavier constituents. To prepare 'wet white' the constituent powders were mixed and glycerin was added. Surfactants could also be included to assist in dispersing the powders.

A 'wet white' formula on these lines, quoted by Poucher,[44] is given in example 18.

	(18) *per cent*
Bismuth subnitrate	5·0
Starch	5·0
Zinc oxide	10·0
Glycerin	15·0
Rose water	65·0

Other more modern formulae omit the bismuth salt and starch, and employ more pigments, fillers and colouring materials to simulate various shades of flesh colour. Examples 19 and 20 will serve as a basis for experiments:

	(19) *per cent*
Zinc oxide	3·0
Chalk (precipitated)	15·0
Kaolin	2·0
Colouring matter	*q.s.*
Glycerin	15·0
Water	65·0
Preservative, perfume	*q.s.*

	(20) *per cent*
Zinc oxide	10·0
Titanium oxide	10·0
Talc	10·0
Colouring matter	*q.s.*
Gum tragacanth (0·5% solution)	25·0
Glycerin	15·0
Water	30·0
Preservative, perfume	*q.s.*

Janistyn[43] quoted a liquid powder formulation of the following composition:

	(21) *per cent*
Sodium carragheenate (medium or high viscosity)	2·0
n-Propyl alcohol	2·0
Propylene glycol	5·0
Water	68·5
Veegum HV	0·5
Talc	10·0
Magnesium carbonate	4·0
Titanium dioxide	1·0
Colour pigments	7·0
Perfume	*q.s.*

Procedure: Wet the carragheenate with propyl alcohol and then dissolve it in the propylene glycol–water mixture. Veegum is then dispersed in the solution, followed by the addition of mixed pigments.

Cosmetic Stockings

This type of aqueous make-up was used during World War II as a leg make-up or liquid cosmetic stocking. The requirement was that the appearance of a treated leg should be very similar to a leg encased in a normal stocking. It was essential that the preparation should not wash away in the rain, nor rub off on to clothing, yet should be easily removable by washing with soap and water.

A basic formula upon which to elaborate a liquid 'cosmetic stocking' is given in example 22.

	(22) *per cent*
Zinc oxide	6·0
Chalk (precipitated)	16·0
Methylcellulose	0·5
Glycerin	16·0
Water	61·5
Colouring matter, preservative, perfume	*q.s.*

More opacity in the finished make-up may be obtained by increasing the proportion of zinc oxide and/or including titanium dioxide, but an obviously artificial effect is undesirable. A little alcohol may be included in order to accelerate drying; the viscosity may be varied by the use of different viscosity grades of methyl cellulose or other cellulosic film-forming material; alternatively alginates or gum mucilages may be included, but care must be taken that the finished preparation is not sticky.

To increase the time during which the pigmented powder remains in suspension (after shaking) while the preparation is being applied to the leg, a few per cent of bentonite or other similar clays may be incorporated.

A certain amount of glycerin or similar non-evaporating and foundation-forming substance is desirable as this improves the adherence of the film of powder to the leg.

Colouring matters usually consist of mixtures of harmless yellow, red, and brown pigments according to the shade desired; in addition some soluble dyes may be included to produce a slight staining effect on the leg and also minimize the appearance of separation between the aqueous and powder phase in the container.

The following formula appeared in the *American Perfumer*:[45]

	(23) *per cent*
Zinc stearate	2·0
Titanium dioxide	3·5
Colloidal aluminium-magnesium silicate gel (Veegum)	20·0
Isopropyl alcohol	6·0
Umber	0·5
Yellow oxide	2·5
Red oxide	2·5
Propylene glycol	1·0
Methylcellulose (1500 viscosity grade)	0·5
Water, perfume, preservative	to 100·0

LIQUID MAKE-UP

Liquid make-up for cosmetic use is another development of the wetted powder which consists essentially of pigments dispersed in a viscous base.

The early liquid make-up preparations were suspensions of pigments in an aqueous alcoholic solution, which required vigorous shaking prior to use to ensure uniform distribution of the product during application.

The basic problem in the preparation of more elegant products of this type is to prevent the sedimentation of constituent pigments by dispersing them in a hydrocolloid base or in a liquid emulsion. The hydrocolloids used for thickening the preparations may be selected from cellulose derivatives, carragheenates, Carbopol 934 or 941, Veegum and others.

The pigments used in liquid make-up preparations are the usual components of powder bases such as talc, kaolin, zinc oxide, titanium dioxide, calcium or magnesium carbonates and others.

In emulsified products, raw materials used included propylene glycol monostearate, glyceryl monostearate, fatty alcohols such as cetyl or oleyl alcohols, isopropyl myristate, lanolin and its derivatives, polyethylene glycols, humectants and others; in general they resemble the make-up cream described in example 17 above.

A liquid make-up formula quoted by Shansky[46] is given in example 24. Viscosity may be adjusted by varying the amount of gum and bentonite.

	(24) *parts*
Propylene glycol	4·40
Polyethylene glycol 400 monostearate	1·92
Preservative	0·32
Gum tragacanth (0·175% solution)	76·68
Bentonite	0·96
White oil	1·20
Oleyl alcohol	6·72
Stearic acid	4·20
Triethanolamine	1·92
Perfume	*q.s.*
Titanium dioxide plus powdered pigments	*q.s.*

Pigments and titanium dioxide are usually in the formula at a level of 5–10 per cent, as in example 25 (the actual amount will depend on the shade desired).

	(25) *per cent*
Isopropyl lanolate	3·50
Isopropyl myristate	4·20
Squalane	1·40
Purcellin oil	2·10
Mineral oil	12·80
Sorbitan oleate	1·00
Veegum (5% solution)	30·00
Propylene glycol	8·00
CMC (1% solution)	20·60
Polyoxyethylene (20) sorbitan mono-oleate	4·00
Water	6·04
Titanium dioxide	4·60
Yellow iron oxide	0·56
Red iron oxide	0·55
Black iron oxide	0·10
Perfume	0·25
Preservative	0·30

STICK MAKE-UP

Liquid make-up products are by far the most acceptable products for face make-up, mainly due to their light application which suits the modern style and their convenience of use (bottle or tube). However, there is a small but significant proportion of the market who prefer a heavier make-up but with the convenience factor as well. This has led to the development of stick make-up, which in essence is a dispersion of pigments in a wax base. A typical formula is shown in example 26.

	(26) *per cent*
Mineral oil	47·65
Paraffin wax	3·50
Beeswax	1·50
Carnauba wax	4·00
Kaolin	9·00
Titanium dioxide	30·00
Yellow iron oxide	2·50
Red iron oxide	1·50
Black iron oxide	0·30
Perfume	0·05

Procedure: Mix the oils and waxes together and heat until a clear solution is obtained. Mix in the colours and pigments gradually with a high-speed Silverson-type mixer. Shade, dispersion and setting point should be checked prior to pouring the product into the appropriate containers.

This stick concept can be extended further to give the cover-up product, used to disguise birthmarks and blemishes. The product is heavily pigmented and is applied like a lipstick.

	(27) *per cent*
Lanolin alcohols	2·8
Ozokerite wax	8·0
Paraffin wax	6·0
Mineral oil	20·2
Isopropyl myristate	10·0
Lanolin	2·8
Titanium dioxide	36·8
Kaolin	8·0
Yellow iron oxide	2·5
Black iron oxide	0·6
Red iron oxide	2·0
Perfume	0·3

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O-T-C Products for Diaper Rash and Prickly Heat

by Farid Sadik

The products shown above through the courtesy of the Henry B. Gilpin Company are for illustrative purposes only.

Diaper rash and prickly heat are acute inflammatory skin conditions that afflict infants and young children. The skin of infants is thinner, less firm and more tender than of the adults. It is not adjusted to external life and is susceptible to inflammation. Due to burning and itching, children become restless and sleep is interrupted by crying episodes. Although these conditions are bothersome and annoying, they can be prevented and treated.

Diaper Rash

Diaper rash is an acute, superficial inflammatory dermatitis which is frequent during the diaper wearing period. It is characterized by erythematous papules, maceration and chafing; the skin is sensitive and painful when touched. The sites of inflammation are the buttocks, groins and inner thighs and folds of joints. This affliction is caused by one or a combination of factors—

1. *Sweat retention*—The frequency of normal urination ranges from one to 20 times daily for infants up to two months old, and one to eight times daily for two-month to two-year-old children.[1] If the wet and fecal-soiled diaper is not soon exchanged with a fresh dry one the diaper region of the skin will remain in contact with moisture causing the skin, the *Stratum corneum,* to become waterlogged. This results in blockage of the orifices of the sweat ducts by keratinous plugs and results in sweat retention which may cause erythematous papules.

2. *Ammonia*—The production of ammonia by urea-splitting bacteria is the most widely accepted theory for the causation of diaper rash. Early in this century investigators recognized ammonia as the causative factor of diaper rash, but none explained the origin of the ammonia.[2,3] In 1921, Cooke attributed the production of ammonia to urea-splitting bacteria which he isolated from the stools of every child in a group of 31 cases of diaper rash.[4] He named the organism *Bacillus ammoniagenes* and described it as an aerobic, non-motile gram-positive bacillus. It is a saprophyte but has the ability to ferment urea to produce ammonia—

$$CO(NH_2)_2 + 2H_2O \rightleftharpoons (NH_4)_2\,CO_3 \rightleftharpoons 2NH_3 + H_2O + CO_2$$

Cooke went a step further and proved experimentally that diaper rash was caused by the ammonia and not by the bacteria itself.

Ammonia causes dermatitis because it raises the pH of the skin and because it saponifies the natural oils of the skin. The defatted skin becomes easily affected by the irritating influence of ammonia. Ammoniacal diaper rash can be diagnosed by the pungent, ammoniacal odor of the diaper and by the erythematous papules present mainly over the buttocks and the inner surface of the thighs.

3. *Mechanical and chemical irritants*—Mothers often have the tendency to have the infant's diapers pinned tightly and usually have the diaper covered with plastic pants. This prevents mothers from knowing when the child is wet and prolongs contact of urine and ammonia with the skin. It also increases humidity and heat in the diaper area because plastic keeps air away from the skin. Trauma can be caused by the constant rubbing of the urine soiled diapers and by the elastic edges of the plastic pants. In chubby children the rubbing of the skin folds can cause trauma.

Feces, urine and soap can act as primary irritants when the skin remains exposed for a relatively long time. Irritation of the anal region is more pronounced in infants who have frequent loose stools or suffer from diarrhea. Feces remaining between the skin folds, if not removed by thorough cleansing, will cause chafing of the skin. The use of strong soap for bathing babies as well as for washing diapers may cause irritation, especially in babies who have sensitive skin. Failure to remove and rinse the soapy solution from between the skin folds and from diapers can aggravate the condition.

4. *Secondary infections*—Cutaneous infection of the diaper region is usually a sequel of untreated dermatitis caused by sweat retention, ammonia, mechanical and chemical irritants. Humidity, temperature, feces and the warm urine-soaked diaper make a good environment and fertile media for the development and multiplication of a variety of infections caused by fungi and bacteria.

Fungal infection of the diaper region is caused most commonly by *Candida albicans* which is a saprophyte and regular inhibitant of the gastro-intestinal tract. The stool is the main source for a candidal diaper rash. It is characterized by the eruption of lesions on the groins, axilla, intergluteal fold and lower abdomen. The lesions are eroded, weeping and surrounded by satellite pustules.

Bacterial infection that affects the

diaper region is usually caused by *Staphylococci*. The infection is characterized by the appearance of vesicles, bullae and pustular and crusted lesions on the already inflamed diaper region of the skin.

Diaper rash also may accompany other dermatologic eczema, seborrheic dermatitis or systemic disease.

Prickly Heat

Prickly heat—also known as heat rash—is an acute dermatitis frequent in infants. It erupts as a consequence of sweat retention resulting from the occlusion of the orifices of sweat ducts. It mostly occurs during hot, humid weather but can erupt when children are overclothed and overcovered in their cribs or when the temperatures of their bedroom and playroom are too warm. Prickly heat is characterized by pinpoint erythematous papulo-vesicles that provoke burning and itching. The parts of the body involved are the neck, shoulders, chest, back and skin folds.

Diaper Rash, Prickly Heat Treatment

The management of diaper rash and prickly heat can be achieved by prophylactic and active treatments.

Prophylactic treatment can be attained by eliminating the causative factors. The pharmacist can play an important role in keeping mothers who come for advice well informed of the causes and how to prevent them from occurring. Mothers should be aware of the fact that the indiscriminate use of medications as the only way of treatment is erroneous. The reliance on drugs alone cannot prevent or stop diaper rash or prickly heat. Indeed, they may hypersensitize the skin or induce therapeutic dermatitis. Thus, the condition is causing the skin to become more vulnerable to secondary infections.

From questioning mothers, the pharmacist can recognize the cause of the condition. Beside explaining the steps that must be taken to prevent diaper rash and prickly heat, he can recommend several products to fit the child's condition. However, should the pharmacist recognize the presence of infections or should the rash persist a physician must be consulted. The persistence of rash may be a signal to secondary infections or a symptom of other disease that need to be diagnosed by the physician.

The prevention of diaper rash has first importance. It is the responsibility of mothers to anticipate and forestall it. The diaper should be changed as soon as it is soiled and at regular intervals. Diapers should be made of unabrasive material and should be loosely pinned to prevent rubbing the skin which results in trauma. Plastic pants should be used as little as possible, and their use at night must be entirely eliminated. In addition to the usual daily bath, the diaper region has to be cleansed after every diaper-change to remove bacterial contamination and fecal remainings. The application of mild ointment or dusting powder is recommended after the thorough cleansing of the diaper area. Mild soap should be used for cleansing as well as for bathing. Skin folds, which entrap sweat and feces, should be cleansed thoroughly and then rinsed with water to insure complete removal of soapy solution. Gentle and thorough drying of the diaper region as well as skin folds is important for keeping the skin free of excessive moisture.

For treating ammoniacal diaper rash it is essential to inhibit the urea-splitting bacteria. This can be deterred by using antiseptic diaper rinse. The soiled diapers are washed with mild detergent and warm water. After rinsing, the diapers are soaked in an antiseptic solution such as methylbenzethonium chloride or benzalkonium chloride for a few minutes, wrung out lightly and allowed to dry. Benzalkonium chloride is available as ten percent concentrate and methylbenzethonium chloride is available as six percent granules. The concentrated solution of benzalkonium chloride should be diluted before use by adding one teaspoonful to two quarts of warm water. The methylbenzethonium chloride solution is prepared by adding one level teaspoonful to two quarts of warm water. When a washing machine is used the diapers are left in the machine after being washed and rinsed. The prepared antiseptic solution is added to the diapers, allowed to soak for a few minutes and then spun dry. A good method of eliminating the urea-splitting bacteria is to boil the cleansed, rinsed diapers for several minutes.

Mothers frequently store the used diapers in a diaper pail until such time as a number have accumulated. In order to keep odor down and inhibit bacteria multiplication it is recommended that a quaternary ammonium chloride solution be added to the diaper pail.

The prevention of prickly heat consists of eliminating the offending factor, namely overheating. Overclothing, as well as overcovering babies, must be avoided. Light clothing and covering is recommended to allow air to reach the skin. During hot weather the frequent removal of clothes for relatively short periods is helpful in keeping the skin dry. Air conditioning the baby's bedroom and playroom helps to lower humidity and temperature. Sweat can be reduced by frequent bathing and the judicious use of bland dusting powder.

Active treatment of diaper rash and prickly heat should be based on the condition of the individual case. Useful products can be classified as protectants, agents to promote healing, antiseptics, antifungal and anti-inflammatory agents.

Protectants—Zinc oxide is a popular ingredient in many preparations used in treatment of diaper rash and prickly heat. It is generally accepted as a material which is protectant with mild astringent and weak antiseptic properties. When applied topically it is relatively non-toxic.

Purified talc, which is a native hydrous magnesium silicate, is used extensively in dusting powders either alone or in combination with other medications. It allays irritation, prevents chafing of the skin and has the ability to absorb sweat. Talc is unctuous and adheres well to skin. Inhalation of zinc oxide and talc by infants could be dangerous. Consequently, mothers should exercise caution when dusting powder is applied to the infant's body. Magnesium stearate is included in formulation of some baby powders because it is unctuous, adheres to skin and acts as mechanical barrier to irritants.

Corn starch is used in dusting powders. In addition to acting as a protective it is a good sweat absorbant. Colloidal oatmeal is employed in different formulations for its soothing and protective action. It allays irritation and itching.

Agents to promote healing—Among the compounds used for this purpose are peruvian balsam, cod liver oil, and vitamins A and D. At one time the use of peruvian balsam was common but its popularity dropped considerably because its continued use may cause sensitization and because of the availability of more effective products. It also stains linen, diapers, and clothes. By virtue of the esters of benzoic acid and cinnamic acid it has a mild bacteriostatic activity. It is stated that it promotes the growth of epithelial cells.[5]

Preparations containing cod liver oil and vitamins A and D have been in use for quite some time for treating inflammation of the skin, burns and diaper rash. It is reported in older literature that these preparations promote healing and stimulate granulation,[6] however, it is difficult to substantiate this in modern literature.

Antiseptics—Secondary infection caused by *Staphylococci* usually respond to local treatment with neomycin, bacitracin and polymixin B sulfate. In addition to antibiotics many

A and D Oin
A and D Cre
Ammens Med
Ammorid Der
Ammorid Dia
Aveeno Baby
Aveeno Bar
Aveeno Collo
Aveeno Ointn
Baby Ointmer
Bab-Eze Pedi
Balmex Baby
Balmex Ointn
Be-Be Cream
Borofax
Caldesene Me
Caldesene Me

Examples of O-T-C Diaper Rash and Prickly Heat Remedies

Product	Manufacturer	Dosage Form	Ingredients
A and D Ointment	White	Ointment	Vitamin A* Vitamin D* Petrolatum-lanolin base*
A and D Cream	White	Cream	Hexachlorophene* Vitamin A* Vitamin D* Lanolin*
Ammens Medicated Powder	Bristol Myers	Powder	Zinc oxide* 8-Hydroxyquinoline* Boric acid* Starch* Talc* Aromatic oils*
Ammorid Dermatologic Ointment	Kinney	Ointment	Zinc oxide* Benzethonium chloride* Lanolin*
Ammorid Diaper Rinse	Kinney	Powder	Methylbenzethonium chloride* Disodium salt of EDTA*
Aveeno Baby Powder	Cooper	Powder	Colloidal oatmeal* Hexachlorophene 0.25% Zinc oxide* Parachlorometaxylenol 0.25%
Aveeno Bar	Cooper	Soap bar	Colloidal oatmeal, over 50% Mild sudsing agent (soap free)* Hypo-allergenic lanolin* Hexachlorophene 2%
Aveeno Colloidal Oatmeal	Cooper	Powder	Oatmeal derivatives*
Aveeno Ointment	Cooper	Ointment	Colloidal oatmeal* Zinc oxide* Hexachlorophene*
Baby Ointment	Massengill	Ointment	Aluminum hydroxide* Zinc oxide* Boric acid* Benzoin* Balsam tolu* Storax* Phenol* Lanolin-petrolatum base*
Bab-Eze Pediatric Creme	AVP	Cream	L-leucine* L-isoleucine* L-methionine* L-phenylalanine* L-tyrosine* DL-methionine* Cysteine hydrochloride* Benzethonium chloride* Talc*
Balmex Baby Powder	Macsil	Powder	Zinc oxide* Purified peruvian balsam* Talc* Starch* Calcium carbonate*
Balmex Ointment	Macsil	Ointment	Vitamin A* Vitamin D* Zinc oxide* Purified peruvian balsam* Bismuth subnitrate* Base containing silicone*
Be-Be Cream	Crookes-Barnes	Cream	Zinc oxide* Hexylresorcinol* Chlorothymol* Calamine* Starch* Silicone*
Borofax	Burroughs Wellcome	Ointment	Boric acid 5% Lanolin*
Caldesene Medicated Powder	WTS	Powder	Calcium undecylenate 15% Talc*
Caldesene Medicated Ointment	WTS	Ointment	Calcium undecylenate 15% Water washable base

(*continued on page 22*)

Examples of O-T-C Diaper Rash and Prickly Heat Remedies (continued)

Product	Manufacturer	Dosage Form	Ingredients
Comfort Powder	Parke-Davis	Powder	Dried potassium alum 1.5% Magnesium carbonate 0.3% Salicylic acid 0.5% Phenol, not more than 0.25% Talc* Corn starch*
Comfortine	Rorer	Ointment	Zinc oxide 2% Calamine 3% Boric acid 2% Lanolin*
Desitin Baby Lotion	Leeming	Lotion	Liquid lanolin* Hexachlorophene* Vitamin A* Vitamin E* Cleansing emulsifier* Wetting agent*
Desitin Ointment	Leeming	Ointment	Cod liver oil* Zinc oxide* Talc* Petrolatum* Lanolin*
Desitin Powder	Leeming	Powder	Cod liver oil* Zinc oxide* Talc* Magnesium oxide* Hexachlorophene*
Desitin Soap	Leeming	Soap bar	Hexachlorophene, over 2% Natural oils*
Diapakare Baby Powder	Canfield	Powder	Diaphen* Corn starch* Sodium bicarbonate*
Diaparene Baby Lotion	Breon	Lotion	Methylbenzethonium chloride 1:1500 Oxycholesterin absorption base
Diaparene Baby Powder	Breon	Powder	Methylbenzethonium chloride 1:1800 Corn starch* Magnesium carbonate*
Diaparene Ointment	Breon	Ointment	Methylbenzethonium chloride 1:1000 Petrolatum* Glycerin*
Diaparene Diaper Rinse	Breon	Granules	Methylbenzethonium chloride 6%
Diaparene Peri-Anal Creme	Breon	Cream	Methylbenzethonium chloride 1:1000 Cod liver oil* Water repellent base
Diaper Rash Baby Cream	Holland-Rantos	Cream	Hexachlorophene* Vitamin A* Vitamin D* Mineral oil* Lanolin* Zinc oxide* Methyl and propyl paraben* Silicone*
Diaper-Sil Creme	Roerig	Cream	Benzalkonium chloride* Panthenol* Dimethylpolysiloxane*
Diaprex Ointment	Moss, Belle Chemists	Ointment	Balsam of Peru* Boric acid* Zinc oxide* Zinc stearate* Water resistant base
Hollandex	Holland-Rantos	Ointment	Cod liver oil* Hexachlorophene* Zinc oxide* Silicone* Lanolin*
Johnson's Baby Cream	Johnson and Johnson	Cream	Mineral oil* Paraffin* Lanolin* White beewax* Ceresin*

(continued on page

Examples of O-T-C Diaper Rash and Prickly Heat Remedies (continued)

Product	Manufacturer	Dosage Form	Ingredients
Johnson's Baby Lotion	Johnson and Johnson	Lotion	Hexachlorophene* Modified lanolin*
Johnson's Baby Oil	Johnson and Johnson	Lotion	Mineral oil* Lanolin*
Johnson's Baby Powder	Johnson and Johnson	Powder	Talc
Johnson's Medicated Powder	Johnson and Johnson	Powder	Hexachlorophene* Bentonite* Kaolin* Talc* Zinc oxide*
Melynor Diaper Rash Ointment	Davies, Rose-Hoyt	Ointment	Peruvian balsam 2% Zinc oxide 10% Petrolatum* Pure beewax Anhydrous wool fat*
Mennen Baby Magic Bath	Mennen	Lotion	Hexachlorophene*
Mennen Baby Magic Cleansing	Mennen	Lotion	Mineral oil* Lanolin*
Mennen Baby Magic Lotion	Mennen	Lotion	Lanolin* Refined sterols* Methylbenzethonium chloride*
Mennen Baby Magic Powder	Mennen	Powder	Methylbenzethonium chloride* Talc*
Mennen Baby Powder	Mennen	Powder	Methylbenzethonium chloride* Magnesium stearate* Talc*
Methakote Pediatric Creme	Borden	Cream	L-leucine* L-isoleucine* L-methionine L-phenylalanine* L-tyrosine* DL-methionine* Cysteine* Talc* Benzethonium chloride*
Mexsana Medicated Powder	Plough	Powder	Hexachlorophene* Corn starch* Kaolin* Camphor* Zinc oxide* Oil of eucalyptus*
Mexsana Skin Cream	Plough	Cream	Camphor* Menthol* Oil of eucalyptus* Oil of cloves* Carbolic acid* Lanolin*
Oilatum Soap	Stiefel	Soap bar	Polyunsaturated vegetable oil 7.5%
Olafsen	Walgreen	Ointment	Cod liver oil* Vitamin A* Vitamin D*
pHisoHex	Winthrop	Emulsion	Hexachlorophene 3% Sodium octylphenoxyethyl ether sulfonate* Lanolin cholesterols* Petrolatum*
Rexall Baby Talc	Rexall	Powder	Talc
Roccal	Winthrop	Solution	Benzalkonium chloride 10%
Soyaloid	Dome	Powder	Colloidal soya complex (52% colloidal protein) with polyvinyl pyrrolidone 2%
St. Joseph Baby Powder	Plough	Powder	Corn starch* Hexachlorophene* Benzethonium chloride* Orthophenylphenol*
St. Joseph Baby Lotion	Plough	Lotion	Hexachlorophene* Methylphenylpolysiloxane* Cetyl alcohol* Mineral oil* Allantoin*

(continued on page 24)

Examples of O-T-C Diaper Rash and Prickly Heat Remedies (continued)

Product	Manufacturer	Dosage Form	Ingredients
Taloin	Warren-Teed	Ointment	Methylbenzethonium chloride* Calamine* Zinc oxide* Eucalyptol* Silicone base*
Tucks Cream	Fuller	Cream	Vitamin A* Vitamin D* Witch hazel 50% Washable base
Tucks Ointment	Fuller	Ointment	Vitamin A* Vitamin D* Witch hazel 50% Non-washable base
Z.B.T. Baby	Glenbrook	Powder	Talc* Mineral oil* Magnesium stearate*
Zincofax Cream	Burroughs Wellcome	Cream	Zinc oxide 15% Petrolatum-lanolin base
Zinc Oxide Paste USP	(Unspecified)	Paste	Zinc Oxide 25% Starch 25% White petrolatum 50%
Zinc Oxide Paste with Salicylic Acid NF	(Unspecified)	Paste	Salicylic acid 2% Zinc oxide paste USP 98%
Zinc Oxide Ointment USP	(Unspecified)	Ointment	Zinc oxide 20% Liquid petrolatum 15% White ointment 65%
* Quantitative statement not provided.			

other medications have been used to combat bacterial infection.

Hexachlorophene is widely used in soaps, ointments, creams and skin lotions in concentration ranging from one percent to three percent for prophylactic and active treatment. It is more effective against gram-positive than gram-negative bacteria. The antibacterial activity of hexachlorophene is not affected by the presence of soap.

Quaternary ammonium chloride compounds are often used as a component of dermatological preparations for treating diaper rash and prickly heat in addition to prophylactic use. They are fast-acting and effective germicides as well as surface-active agents. However, because they are incompatible with soap their germicidal activity is reduced. Elimination of soap contaminations from diapers as well as skin is important for gaining the germicidal activity.

Boric acid has been used extensively for treatment of a variety of skin disorders including diaper rash and prickly heat. It is used in ointments and dusting powders either alone or in combination with other ingredients because of its purported mild bacteriostatic and fungistatic activity. Its use, however, has decreased considerably because its toxic effects have been recognized. It has been established that when it is applied topically to a large area of broken skin or a weeping surface the absorption of boric acid will take place resulting in boric acid poisoning which in many cases proved to be fatal.[7]

Antifungal agents—Mystatin, amphotericin B are effective in the topical treatment of cutaneous candidiasis. All cases of candidal diaper rash treated with dusting powder consisting of 100,000 units of nystatin per gram of talc responded well.[8] A two percent amphotericin ointment cured 12 out of 15 cases of candidal diaper dermatitis.[9] Hydroxyquinoline is employed topically for its antibacterial and antifungal action. Calcium undecylenate is employed mainly as antifungal agent.

Anti-inflammatory agents—Steroids are the drugs of choice to combat inflammation associated with dermatitis. The therapeutic effect of antibacterial and antifungal agents is enhanced when combined with steroids.[10]

Conclusion

The pharmacist can serve—in his capacity as a member of the health team—those who seek his advice. He should be available for reliable information concerning elimination of the conditions predisposing diaper dermatitis and prickly heat. Prevention of these afflictions is the first and most important step toward attaining successful treatment. Recommendation of the use of a specific product must come after the condition has been determined because each diaper dermatitis requires specific designation and appropriate therapy. The pharmacist, however, should refer his clients to a physician if there is any probability of complications.

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Patents

In this book, the patent literature has been treated as a source of information. Certain formulae and processes have been included in the interests of science, notwithstanding the existence of actual or potential patent rights.

Mention of a patent does not necessarily indicate that the patent is currently in force, but in so far as materials and processes are protected by letters-patent, their inclusion neither conveys nor implies licence to manufacture. Each manufacturer should ascertain for himself the patent position existing in his own country at that time.

Legislation

Legislation concerned with permitted materials, limitations on use and methods of sale of toilet preparations is in a state of continual change, notably in the USA and the European Economic Community. While every effort has been made to take count of the latest position, inclusion of a particular ingredient in any one illustrative formula cannot be taken as indicating that this formula will be within the limits of legal permission in any one country at the time when it may be under consideration. As with patents (above) every manufacturer must ascertain for himself the legal position existing in his country or that to which he exports at that time.

Harry's Cosmeticology

Seventh edition

Edited by
J. B. Wilkinson, MA, BSc, CChem, FRSC
R. J. Moore, BSc, CChem, MRSC, MIInfSc

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Chapter Twelve

Shaving Preparations

The typical man tends to regard the removal each day of 20 000–25 000 terminal hairs protruding 250–500 μm from the skin at angles of 30 to 60 degrees[1] and covering a facial area of 250 cm^2, as something of a chore. To minimize the trauma of shaving, a wide range of preparations is now available that prepare the beard and face for shaving, increase speed and comfort during the shave and confer a feeling of well-being after shaving. The choice of shaving preparation is highly individualistic; however, it is generally recognized that different forms of beard preparation are required for 'wet' (razor blade) and 'dry' (electric razor) shaving. This results from the contrasting mechanisms of hair cutting, which can be inferred from the appearance of the ends of hairs cut by the two implements. The description of shaving preparations has therefore been divided into three sections: wet shaving preparations, dry shaving preparations and after-shave preparations.

WET SHAVING PREPARATIONS

Introduction

The main functional requirements of a wet shaving preparation are to soften the beard, to lubricate the passage of the razor over the face and to support the beard hair. In addition, the preparation should be non-irritating to the skin, should assist in removing shaving debris from the face, should be stable over a range of temperatures, resistant to rapid drying out and collapse, non-corrosive to the razor blade and easily rinsed from the razor and face. There is good evidence for the hair softening and lubrication functions of the shaving preparation, but little has been reported on the hair-supportive role.

Beard Softening

Beard softening results from changes in the mechanical properties of hair by absorption of water. Hair absorbs 31 per cent of its dry weight of water at 100 per cent relative humidity; the relationship between water absorption and relative humidity is non-linear and the swelling of hair is highly anisotropic.[2] The force required to cut water-saturated beard hair is about 65 per cent less than that for dry hair.[3]

The hydration of hair is accelerated by increases in temperature; however, views differ on the time taken to hydrate hair completely. This ranges from 2 minutes at room temperature, as measured by the force required to cut beard hair,[3] through $2\frac{1}{2}$ to 3 minutes at 49°C (120°F), as measured by creep of scalp hair extrapolated to the thicker beard hair,[1] to 6 minutes at 43°C (110°F) as measured by changes in the elasticity of hair.[4]

The established view on beard softening is based on measurements of the creep and elasticity of hair, supported by practical shaving tests. This suggests that the rate of softening of the beard can be increased by the addition of a wetting agent to the water, increasing the pH of the water and the removal of sebum from the hair. More recent work[3] suggests that the force required to cut the hair is not reduced by the use of wetting agents, soap solutions or shaving creams below the value for water alone. Similarly, changing the pH over the range 4·0 to 9·1 and the presence of sebum on the hair do not influence the cutting force. The importance of the shaving preparation in beard softening clearly differs according to which set of results is accepted.

Skin Lubrication

There is little published work on the contribution of skin lubrication to the comfort, closeness and speed of wet shaving. Early work by Naylor[5] on the coefficient of friction of plastic materials on skin indicated that friction was lower if the skin was dry, greasy or very wet, but higher if the skin was merely moist. Other work has shown that skin friction is reduced by surfactant solutions, mineral oils[6] and silicone fluids.[7] The force of friction on skin is not a linear function of the normal load[7,8] as suggested by Amonton's law, the deviations being attributed to the elastic behaviour of skin.

The frictional force between a razor blade and facial skin has been measured using a razor with built-in strain gauges.[9] The frictional properties of dry skin were shown to be higher than for wet skin although the absolute values vary for different areas of the face. The type of shaving preparation used does influence the frictional properties to the extent that it is possible to distinguish between different aerosol shaving foam formulations. It is generally found that the second stroke of the razor over a given part of the face yields a higher frictional force than the first stroke, presumably because the first stroke effectively removes most of the shaving preparation. Shavers apparently adjust the applied load on the razor according to the shaving preparation used; the lower the frictional force between the razor and skin, the higher is the applied load and the closer the resultant shave.

One can only speculate on the mechanism of lubrication by the shaving preparation since it depends on the load applied to the razor, the area of contact with the face, the velocity of the razor across the face and the viscosity of the preparation. At high loads per unit area and low shaving speeds, boundary lubrication is likely to predominate so that for a low coefficient of friction the shaving preparation should have a high viscosity and form a condensed film which interacts strongly with skin to preserve the integrity of the lubricant film. At low loads per unit area and high shaving speeds, hydrodynamic lubrication is likely to predominate. The viscosity of the shaving preparation should be high enough to give a film thickness sufficient to prevent asperity contact, but thereafter the viscosity should be as low as possible.

Beard Softening Cream

For many, washing the face with soap and water is an adequate pre-shave preparation for the attainment of a satisfactory shave with a razor blade and

shaving foam. Where this is felt to be inadequate, pre-shave preparations are available to wet and soften the beard and to lubricate the skin; these are often referred to as beard softeners. They are particularly helpful to those with easily abraded skin or large diameter beard hair (since the hydration time varies as the square of the radius of hair, assuming that the diffusion of water into hair obeys Fick's laws). Brushless, non-lathering shaving creams, although satisfactory in terms of their lubricating action, often do not soften the beard sufficiently quickly or adequately. The application of a beard softener containing soaps, synthetic surfactants or possibly urea prior to the application of a brushless cream will allow a more complete wetting and softening of the beard and ensure a close and smooth shave. Such a formulation may contain a lime soap dispersing agent to improve the wetting action in hard water, a soap-compatible anti-bacterial agent, menthol and a preservative.

A beard softening cream recommended by Keithler[10] has the following composition:

	(1) *per cent*
Stearic acid	13·8
Stearyl alcohol	2·0
Isopropyl palmitate	1·9
Paraffin oil	2·0
Lanolin	2·0
Tween 60	2·4
Span 60	1·0
Triethanolamine	1·0
Dupanol C	1·0
Water	72·4
Perfume	0·5

Bell[11] gives another example of a beard softening preparation with the following composition:

	(2) *per cent*
Coconut oil fatty acids, double distilled	4·20
Oleic acid (with low linoleic acid content)	5·60
Propylene glycol	5·00
Triethanolamine	2·85
Monoethanolamine	1·26
Tergitol NPX	2·00
Demineralized water	79·09

Procedure: Mix the fatty acids together and stir into propylene glycol. Add the amines and stir until a clear solution is obtained. Finally mix in the Tergitol and perfume if required, followed by the water.

Tergitol NPX (alkyl aryl polyethylene glycol ether) is used in example 2 to disperse insoluble lime soaps and to improve the wetting action in hard water. Pre-shave liquids, creams and gels based solely on synthetic surfactants have been developed from hair shampoo formulations and these are particularly effective beard softeners in hard-water areas.

Lather Shaving Cream

Criteria for a Good Lather Shaving Cream

The undoubted success of foamed shaving preparations is probably due to their economy in use and ability to supply water to the beard by drainage through the plateau borders formed at the junctions of bubbles in the foam, thereby maintaining the hair in a fully water-saturated condition. The requirements of a good lather shaving cream are as follows:

(1) It must produce a rich copious lather composed of small bubbles.
(2) It must be non-irritant.
(3) It must have good wetting properties.
(4) It should be smooth, soft and entirely free from lumps.
(5) It must adhere readily to both face and brush and yet be easily removed on rinsing.
(6) It must retain a satisfactory consistency and texture over all temperature conditions likely to be encountered in use.

When evaluating foamed shaving preparations, such as lather shaving cream or aerosol shaving foam, attention should be paid to be following points:

Ease of transfer to the face.
Ease of spreading on the face.
Wetting and drainage properties of the foam.
Comfort and closeness of shave.
Foam texture, rigidity and rheology.
Foam stability.
Ease of removal of the lather and shaving debris from the razor and basin.
Acceptability and compatibility of the perfume.
Compatibility with the container.
Effect on the life of the razor blade.

Formulation

Lather shaving creams are concentrated dispersions of alkali metal soaps in glycerol and water. To maintain the desired level of foamability, consistency and product stability, careful control of the manufacturing process is essential. Even the slightest change to the formulation or manufacturing procedure can result in a disastrous phase separation of the cream at slightly elevated temperatures. One must therefore be prepared for problems in the scale-up of laboratory formulations.

Lather shaving creams normally contain 30 to 50 per cent soaps. Formulations based on stearic acid alone do not produce a sufficiently voluminous lather and it

is usual to add some coconut oil fatty acids. The ratio of stearic acid to coconut oil varies considerably in different products but the inclusion of about 25 per cent coconut oil with 75 per cent stearic acid will usually be found satisfactory. A mixture of sodium and potassium hydroxides is used to saponify the fatty acids. It has been suggested[12] that a 5:1 ratio of potassium hydroxide to sodium hydroxide with 3–5 per cent free fatty acids will give shaving creams of the correct degree of plasticity. A cream containing a high level of sodium soaps tends to be thick and stringy, from which it is often difficult to produce a good lather. Lather creams can be made with potassium soaps alone but these tend to be less stable.

In order to prevent premature drying out of the cream, up to 15 per cent of a humectant is usually added. This is normally glycerol, but sorbitol or propylene glycol can be used. Humectants also have the effect of making the creams softer; propylene glycol has the greatest influence on the texture of the cream. An improvement in the properties of the cream and the lather has been claimed[13] by replacing glycerol with 1,3-butylene glycol. Emollients such as lanolin, cetyl alcohol, mineral oil and fatty acid esters should be kept to a low level (1 per cent) if the lathering properties are not to be impaired. Other additives to lather shaving creams, such as synthetic surfactants as foam stabilizers, cooling agents, antibacterial agents, etc., are discussed more fully under aerosol shaving foams.

The pH value of a lather shaving cream is generally around 10. The apparent paradox of a high pH and free fatty acid can be explained in terms of the mixing process. Pockets of unneutralized alkali remain, even under well-controlled manufacturing conditions, because of the high viscosity of the product. As part of the quality control on lather shaving creams, the level of free fatty acid should be determined as a check on the efficiency of mixing during manufacture. The free fatty acid level is one of the factors which influences the maximum temperature at which the cream retains a stable consistency. Above this temperature, free fatty acid rises to the surface of the product, in a similar manner to the creaming of an emulsion, and the functioning of the cream is seriously impaired.

Free fatty acids and the less water-soluble stearate soaps are responsible for the characteristic pearlescence of lather shaving creams. The pearlescence is a result of the formation within the cream of liquid crystalline phases which, in addition to improving its appearance, can increase the stability of the foam generated. The rate at which the liquid crystalline phases form depends on the method of manufacture, in particular the rate of cooling and the amount of stirring. It is normal practice amongst manufacturers to store the cream for some time before packing to allow the structure to develop. The slight change in the consistency and foam stability during the immediate post-manufacturing period should be taken into account when testing production batches of lather shave cream.

Much of our knowledge on lather shaving creams is still empirical; however, further insight may be obtained by consulting the literature on soap manufacture. The following formulation will serve as a guide to experimentation, but the manufacture of a good shaving cream, which will stand up to various climatic conditions, is very much an art.

	(3) *per cent*
Stearic acid	30·0
Coconut oil	10·0
Palm kernel oil	5·0
Potassium hydroxide	7·0
Sodium hydroxide	1·5
Glycerin	10·0
Water	36·5
Perfume	*q.s.*

Procedure: Mix half of the stearic acid with the oils, melt by steam heat, and bring to a temperature of 75°–80°C. Run in the alkali, water and glycerin and stir well until saponification is complete. The remainder of the melted stearic acid is now added together with any water which may have been lost during manufacture. The perfume is added at 35°C.

An Atlas formula quoted by deNavarre[14] is as follows:

	(4) *per cent*
Stearic acid	36·0
Coconut oil	9·0
Potassium hydroxide	8·0
Sodium hydroxide	1·0
Sorbitol (70% solution)	3·0
Water	43·0
Preservative, perfume	*q.s.*

Procedure: Heat the coconut oil to 75°–80°C. Dissolve the alkalis in half of the water and add to the coconut oil. When saponification is complete, add melted stearic acid (70°C) in a thin stream followed by the sorbitol solution, preservative and the remainder of the water. The mixture is then cooled. The perfume may be added at 35°C, or after the emulsion has cooled to room temperature. A check is carried out for completeness of saponification and the free fatty acid content is adjusted to between 3 and 5 per cent. The product is eventually packed into tubes.

Lather Shaving Stick

A lather shaving stick can be prepared from a mixture containing 80 per cent fatty acid soaps, 5–10 per cent glycerol and 8–10 per cent water. The ratio of the fatty acids and the ratio of potassium to sodium soaps should be similar to those described under lather shaving creams. After mixing, the composition is chipped, dried and milled with any other components required, such as perfume, colour or an opacifier. The soap flakes are packed to the desired shape using a soap plodder.

Aerosol Shaving Foams

Aerosol shaving foams are oil-in-water emulsions in which propellant droplets, liquefied under pressure, form a substantial part of the oil phase. When the

emulsion is discharged to the atmosphere, the dispersed propellant droplets vaporize, producing a foam consisting of propellant vapour bubbles surrounded by an aqueous surfactant phase.

Some of the early patents on aerosol shaving foams provide some useful pointers to the influence of the soap composition on the appearance and properties of the foam. The first aerosol shaving foam patent, granted to Spitzer,[15] protected the use of fluorocarbon propellants in aqueous soap solutions enclosed in a pressure-resistant container. Triethanolamine stearate at levels of 8–12 per cent was given as the preferred soap together with smaller amounts of triethanolamine soaps of coconut fatty acids to prevent gelling at low temperatures. Potassium soaps were also said to give satisfactory shaving foams but sodium stearate can only be used at very low concentrations because of its tendency to gel. A later patent granted to Colgate-Palmolive[16] suggested that triethanolamine soaps alone do not make a satisfactory aerosol shaving foam because of a tendency for the emulsion to foam inside the container. As a result, the dispensed foam contains large bubbles and a substantial proportion of the emulsion cannot be expelled from the container. The foams described in the patent contain from 4 to 15 per cent soaps, mainly triethanolamine stearate with minor proportions of potassium and sodium stearates, as in example 5.

	(5) *per cent*
Triethanolamine stearate	8·0
Sodium stearate	1·0
Potassium stearate	4·6
Water	72·5
Perfume	0·9
Borax	0·5
Propellant (fluorocarbon)	12·5

Another patent granted to Colgate-Palmolive[17] claimed that aerosol shaving foams containing less than 4 per cent of potassium soaps produced the best results in softening hair and reducing its resistance to cutting by the razor blade. Soaps of mono- and diethanolamines were also considered suitable for this purpose, but triethanolamine soaps were found to be ineffective. Since the foam produced by such dilute soap solutions was rather unstable, synthetic thickening agents were included in the compositions. Particularly preferred are water-soluble salts of polyacrylic acid and its derivatives, with a mean molecular weight between 100 000 and 200 000, used at concentrations ranging between 0·5 and 3 per cent. These polymers also provide additional lubrication for the razor blade on skin. A ratio of stearic to coconut fatty acid of 80:20 was claimed to give a better beard-softening effect than other fatty acid mixtures when used at low concentrations. A large proportion of free fatty acid is retained to improve lubricity and foam stability. Other lubricants such as cetyl alcohol or glycerol monostearate are also incorporated to improve the feel of the skin after shaving, while nonionic emulsifiers are present to enhance the emulsification of the free fatty acid.

An example of a shaving foam concentrate from the patent had the following

composition:

	(6) *per cent*
Potassium soap from stearic acid/coconut oil fatty acids (80:20)	1·5
Potassium polyacrylate (polyacrylic acid mol. wt 100 000–200 000)	1·0
Polyvinylpyrrolidone	0·5
Stearic acid/coconut oil fatty acids (80:20)	3·0
Castor oil	3·0
Lauric acid diethanolamide	0·5
Polyoxyethylene sorbitan monolaurate	0·5
Perfume	0·5
Water	89·5

Guidance on Formulation

The following general guidance can be given in the formulation of aerosol shaving foams.

Fatty Acids. Saturated long-chain fatty acids containing 12 to 18 carbon atoms at a level of 7–9 per cent are the main components of aerosol shaving foams. Lower-molecular-weight fatty acids such as those found in unstripped coconut oil cause skin irritation. The ratio of the fatty acids can be varied widely to produce foams with different physical properties. The presence of stearic acid is not essential to an aerosol foam as might be inferred from the early patents. A high proportion of stearic acid in the fatty acid mixture tends to give stiffer foams and a reduction in the number of shaves per can. Replacing some of the stearic acid with lauric acid tends to produce softer foams and improves the expulsion characteristics.

Bases. Triethanolamine, potassium hydroxide or mixtures of the two are the preferred bases for the saponification of the fatty acids. Sodium hydroxide is rarely used and then only as a minor constituent. Mono- and diethanolamines are used occasionally but care is needed to avoid skin irritation. Triethanolamine soaps tend to give closer-knit foams than potassium soaps, particularly with fluorocarbon propellants.

It is common practice to adjust the quantity of base so that the formulation contains 1–3 per cent free fatty acid. The free fatty acid can improve the appearance and lubricity of the foam and, by complexing with the soap, increase foam stability. However, this may be at the expense of reducing the amount of available foam and increasing the rate at which the foam dries out on the face.

Surfactants. A wide variety of anionic and nonionic synthetic surfactants can be used in shaving foams to improve such properties as the emulsion stability (for example, self-emulsifying glycerol monostearate), the wetting properties of the foam (for example, sodium lauryl ether sulphate), the water dispersability of the foam and shaving debris (for example, polyethoxylated fatty alcohols), the foam stability (for example, lauric diethanolamide) and emolliency (for example, ethoxylated lanolins). Because of the complex nature of the interactions between surfactants, soaps and free fatty acids, their interfacial properties in the emulsion and foam are not easily predicted.

Humectants. Polyols such as glycerol, sorbitol or propylene glycol are usually added to shaving foam concentrates at a level of 3–10 per cent. By their ability to bind water, they reduce the tendency of the foam to dry out on the face.

Lubricants. To assist the passage of the razor over the face and to provide emolliency, additional lubricants such as mineral oils, silicone fluids, lanolin or isopropyl myristate can be included at a level of 1 to 2 per cent, to supplement the effects of the free fatty acid. Water-soluble polymers such as polyvinyl pyrrolidone, sodium carboxymethyl cellulose or polyacrylic acid and its derivatives can also improve lubrication and increase foam stability. Polyvinylpyrrolidone is said to act as an anti-irritant, that is, to reduce the irritancy caused by other compounds.

Propellants. Aerosol shaving foams contain either 7–10 per cent fluorocarbon propellant or 2·8–3·5 per cent hydrocarbon propellant. The fluorocarbon propellants are usually 40:60 to 60:40 weight ratio blends of dichlorodifluoromethane and dichlorotetrafluoroethane. The hydrocarbon propellants are mixtures of *n*-butane, isobutane and *n*-propane.

The higher the concentration of propellant, the lower the foam density, the stiffer the foam and the greater the number of shaves that can be obtained from a given weight of the emulsion. Foams having a density less than 65 g l^{-1} are likely to be difficult to spread on the face and have little beard-softening capability.

In spite of the higher cost, fluorocarbon-propelled shaving foams became very popular, possibly because of the relative ease of forming close-textured, stable foams. Following the Rowland and Molina[18] hypothesis of stratospheric ozone depletion by fluorocarbon propellants and legislation in the USA, all US aerosol shaving foams are now based on hydrocarbon propellants. The best selling UK aerosol shaving foams are also based on hydrocarbon propellants.

Perfume. Soap-compatible perfumes are used at a level of 0·15–0·65 per cent.

Cooling Agents. Physiological cooling agents are often added to shaving foams to counteract the 'after-glow' associated with shaving. The most frequently used cooling agent is menthol at a concentration of 0·05–0·2 per cent. The volatility of menthol means that its cooling effect on skin is transient and its dominant odour is almost impossible to mask. A group of compounds ranging in chemical type from carboxamides to ureas to phosphine oxides have been shown to possess physiological cooling properties.[19] Many are as effective as menthol but without the disadvantages associated with the volatility of menthol. At a level of 0·1–0·2 per cent in shaving foams, the cooling effect can last for 5–15 minutes after application.

Colour. Foams may be coloured by the use of D&C or FD&C dyes. A very low concentration should be used to avoid staining the skin and towel.

Preservatives. Many shaving foams do not require a preservative; however, when necessary 0·2 per cent of a mixture of methyl and propyl *p*-hydroxybenzoate should suffice.

Antioxidants are sometimes required to avoid rancidity in formulations containing even low levels of unsaturated compounds.

Corrosion Inhibitors. Again these are not normally required with suitably lacquered containers. Borax (0·04 per cent, 10 mol) can be used with tinplate containers and 0·25 per cent of sodium silicate 35° Be solution with aluminium containers.

Bacteriostats, etc. 0·05 per cent trichlorohydroxydiphenyl ether (Irgasan DP300) and 0·05 per cent allantoin should reduce skin infections and promote healing of cuts.

Pilomotor Agents. It is claimed that a closer shave can be obtained by incorporating into the shaving preparation compounds having pilomotor activity—that is, ability to cause the contraction of the arrectores pilorum (hair follicle muscles). This contraction causes the beard hair to be pushed farther above the skin surface line by about 0·2–0·3 mm. A hair cut in the elevated position will retract below the skin surface as the follicle muscle returns to normal. Such patented compounds included: imidazolines,[20] for example, 2-(2′,5′-dimethoxy-4′,6′-dimethylbenzyl)-2-imidazoline; 2-amino-imidazolines;[21] morpholines,[23] for example 2-(3′-hydroxyphenyl)-morpholine; and 2-(phenylamino)-1,3-diazacyclopentenes-(2).[23]

A number of the above compounds can also be used to the same effect in lather shaving creams, brushless shaving creams and pre-electric shave lotions.

A statistical study of the formulation of aerosol shaving foams[24] examined the importance of a number of variables such as soap concentration, fatty acid type, free fatty acid concentration, polyol type and concentration, and propellant type and concentration. The concentrate was evaluated in terms of viscosity, pH, density and stability, while the discharge properties and foam were evaluated in terms of the number of shaves per can, residue in the can after discharge, foam density, foam strength, drying time and bubble size. A number of the findings of the study have been included in this section.

Example Formulations

Fluorocarbon-propelled shaving foam		(7) *per cent*
A	Stearic acid	5·6
	Palmitic acid	2·2
	Isopropyl myristate	1·0
	Coco monoethanolamide	0·3
B	Sodium lauryl ether sulphate (40% solution)	3·5
	Triethanolamine	3·9
	Glycerol	5·0
	Water (deionized)	78·5
	Perfume	*q.s.*
	Concentrate	91·5
	Propellants 12/114 (40:60)	8·5

Aerosol shaving cream (Croda Chemicals Ltd[25])		(8)
		per cent
A	Stearic acid	4·0
	Lauric acid	2·0
	Liquid lanolin (Fluilan)	1·0
B	Cromeen*	3·0
	Triethanolamine	2·5
	Water (deionized)	87·5
	Perfume	*q.s.*
	Concentrate	92·0
	Propellants 12/114 (40:60)	8·0

* Cromeen (Croda Chemicals Ltd) is a substituted alkyl amine derivative of various lanolin acids.

Hydrocarbon-propelled aerosol shaving foam		(9)
		per cent
A	Palmitic acid	5·0
	Lauric acid	1·0
B	Sodium lauryl sulphate	1·0
	Polyethylene glycol (400) monolaurate	0·5
	Polyacrylic acid (40% aq.) mol.wt 100 000	1·5
	Triethanolamine	2·0
	Potassium hydroxide	0·8
	Glycerol	5·0
	Water (deionized)	83·2
	Perfume	*q.s.*
	Concentrate	96·9
	Propellants, isobutane/propane	3·1

Procedure: The general procedure for making all aerosol shaving foams is to heat parts A and B separately to 75°C. Add A to B with vigorous stirring and allow to cool to 35°C, when the perfume is added. The aerosol container is charged when the concentrate has reached room temperature.

Consistent Aerosol Shaving Foam

The properties and expulsion characteristics of aerosol shaving foams change significantly as the container is emptied. Typically, the last 10–15 per cent of the product is wet and runny and may be poorly expelled. This is a familiar problem to the aerosol formulator and one which the consumer has reluctantly learned to accept. It is not possible to overcome this problem just by increasing the propellant content, since this causes the foam initially dispensed to be unacceptably stiff and dry. An interesting solution proposed by Mace and Carrion[26] involves the use of a concentrate formulation which absorbs just enough liquid propellant to give foam of the correct density. Excess propellant is added to form a discrete reserve layer which can supply all the vapour needed to fill the increasing head space. Hence the foam-forming composition remains unchanged as the container is emptied. This approach may impose constraints on the formulation and it would be necessary to educate the consumer not to shake the container before use. A versatile but relatively expensive means of obtaining a

consistent product is provided by the use of a barrier pack, in which the propellant providing the driving force to expel the liquid concentrate is separated from the foam-generating composition by either a piston or a flexible bag. Foams with very uniform properties throughout the life of a barrier pack have been reported.[27] Such a container is used in the post-foaming gel example.

A novel means[28] of maintaining the consistency of an aerosol foam is to use propellant-swollen rubber as a source of additional propellant. Propellant vapour is released from the rubber only when the vapour pressure in the head space falls. Hence the properties of foam dispensed from a full container are unaffected by the presence of additional propellant. When the emulsion is expelled, the head space volume increases and there is a small but sharp drop in vapour pressure. The vapour pressure is restored to slightly below the original value by the release of vapour directly or indirectly from the reservoir and not solely from the emulsion. In this way the ratio of concentrate to propellant in the emulsion, which determines foam density, is not reduced to the same extent with the reservoir as would normally be the case.

The benefits of using a rubber reservoir have been demonstrated by the following formulation:[29]

	(10)
	per cent
Palmitic acid	5·0
Potassium hydroxide	1·0
Sodium lauryl sulphate	2·5
Lauric diethanolamide	1·5
Polyethylene glycol (6000) monostearate	2·0
Water (deionized)	88·0
Fill for a 6 oz aerosol container	*weight (g)*
Concentrate	177·0
Butane 40 propellant	7·6
Ethylene/propylene rubber	3·0

A conventional package without the reservoir would contain 5.1 g propellant (Butane 40) and 177 g concentrate.

After an appropriate period of storage to allow absorption of some of the propellant by the rubber, the total volume of usable foam was 25 per cent greater when the reservoir was used and the expulsion characteristics remained satisfactory until the container was empty. The proportion of usable contents was increased by the use of the reservoir from 79 per cent to over 95 per cent.

Heated Shaving Foam

The interest in heated shaving foams derives from the improvement in beard softening as a result of increasing the temperature. Heated shaving foam can be obtained either by an exothermic chemical reaction between components which are kept separate within the aerosol container or by bringing the foam into contact with a heat exchanger connected to a hot water supply. Products relying on an exothermic redox reaction require a dual dispensing aerosol value, the inner compartment containing hydrogen peroxide and the outer compartment containing the soap solution, propellant and a pyrimidine, a thiourea, a sulphite or a thiosulphite.

Whatever the means of heating the foam, conventional aerosol shaving compositions are generally unsuitable because at higher temperatures these form large unstable bubbles and the foam lacks the body necessary for satisfactory shaving. Compositions that are claimed to be suitable for heated aerosol shaving foams[30] are based on aqueous solutions of triethanolamine stearate, superfatted with free stearic acid. The presence of lower-molecular-weight fatty acids tends to reduce the stability of the foam at elevated temperatures. This can be compensated for to some extent by increasing the concentration of stearic acid which has the ability to thicken the heated soap solution. The inclusion of propylene glycol or of nonionic surfactants, which will produce much richer and more viscous foams at room temperature, tends to give foams of a watery consistency at elevated temperature.

Satisfactory formulations can be obtained with 8–15 per cent triethanolamine stearate, 1 per cent triethanolamine coconut oil soap and 2 or 3 per cent stearic acid. At lower levels of triethanolamine stearate (7–12 per cent) a satisfactory composition will be obtained with 2 per cent triethanolamine coconut oil soap and 3 or 4 per cent stearic acid.

Scum-free Aerosol Shaving Foam

Soap-based shaving preparations leave on the basin and razor an unsightly deposit that is not readily rinsed away. The deposit, known as lime soap curds or scum, is particularly noticeable in hard-water areas and consists of water-insoluble calcium and magnesium soaps and free fatty acids. The deposit can be reduced by the addition of lime soap dispersing surfactants to a conventional formulation. Even the best lime soap dispersing agent should be present at two to three times the concentration of soap to prevent scum formation. Formulations containing low concentrations of soap and high concentrations of surfactant produce unstable foams. It is possible to restore stability to the foam by the addition of long-chain fatty alcohols such as myristyl alcohol.[31] An example of a scum-free aerosol shaving foam containing a low concentration of soaps is as follows:

		(11) *per cent*
A	Palmitic acid	1·95
	Myristic acid	0·62
	Myristyl alcohol	2·10
B	Polyoxyethylene (20) cetyl ether	5·23
	Lauric diethanolamide	5·23
	Propylene glycol	0·82
	Glycerol	3·54
	Triethanolamine	1·54
	Water (deionized)	78·97
	Perfume	*q.s.*
	Concentrate	91·5
	Propellants 12/114 (40:60)	8·5
or	Concentrate	97·0
	Propellant (Butane 48)	3·0

Soap-free Aerosol Shaving Foams

The improvement in the foam stability in example 11 is brought about by molecular complex formation between the long-chain fatty alcohol and the polyoxyethylene fatty ether. The interaction of long-chain fatty acids and fatty alcohols with polyoxyethylene fatty ethers in fluorocarbon propelled shaving foams has been investigated by Sanders.[32] Many of these soap-free formulations showed increases in emulsion viscosity and stability and in foam stability and stiffness. However, it has been observed that many soap-free emulsions undergo an irreversible phase separation when maintained at 37°C for a few weeks, such that, even after vigorous shaking to re-emulsify the solid phase, the contents cannot be expelled as a foam.

Certain nitrogen-containing surfactants in combination with myristyl alcohol are claimed[33] to form stable soap-free aerosol shaving foams which do not undergo irreversible phase separation when stored at elevated temperatures. Such foams do not form a deposit in hard water and will often completely disperse the scum formed by the pre-shave wash with soap. With soap-free formulations it is possible to use hypoallergenic surfactants and the pH can be adjusted to the slightly acid value of skin.

An example of a soap-free aerosol shaving foam is as follows:

		(12) *per cent*
A	Myristyl alcohol	2·1
B	Dicarboxylated lauric imidazoline 40% solution (Cycloteric DL)	5·1
	Polyethylene glycol (1000) monolaurate	5·5
	Propoxylated polyol (Emcol CD-18)	0·7
	Glycerol	5·0
	Water (deionized)	81·6
	Perfume	*q.s.*
	Citric acid	*q.s.*
	Concentrate	97·0
	Propellant (Butane 48)	3·0

Procedure: Heat parts A and B separately to 75°C. Add A to B with vigorous stirring. The perfume is added after cooling to 35°C. The pH of the concentrate is adjusted to the desired value by the addition of citric acid.

A soap-free aerosol shaving foam containing anionic sarcosinate surfactants, given in Croda Chemicals Technical Literature,[34] is as follows:

		(13) *per cent*
A	Fluilanol	5·0
	Crodaterge LS	3·0
	Crodaterge OS	4·0
	Pentol mineral oil	1·0

		per cent
B	Propylene glycol	5·0
	Triethanolamine	1·0
	Water (deionized)	81·0
	Perfume	*q.s.*
	Concentrate	95·0
	Propellant isobutane/propane	5·0

Post-foaming Aerosol Gel

Products of this type are discharged from an aerosol container as a stable gel which, when spread on the face, is claimed to improve the wetting of the skin and beard. The foam is subsequently formed *in situ* on the surface of the skin by the vaporization of low-boiling-point aliphatic hydrocarbons. The product is packaged in an aerosol container with a barrier to separate the post-foaming gel from the propellant required for expulsion. The barrier pack ensures that a homogeneous gel is discharged, substantially free of bubbles, which can produce a self-generated lather of uniform consistency and density throughout the life of the product. The post-foaming gel consists essentially of an aqueous dispersion of soaps, water-soluble gelling agents and a post-foaming agent having a vapour pressure of 6–14 psi (41–96 kPa) at 37°C, for example saturated aliphatic hydrocarbons or halogenated hydrocarbons. Miscellaneous additives such as humectants, emollients, foaming aids, perfume, etc., can also be included in the formulation.

Two examples of post-foaming gels of different foam stiffnesses, given in a patent assigned to S.C. Johnson & Son Inc.,[35] had the following compositions:

	(14) *per cent*	(15) *per cent*
Stearic acid (95% purity)	2·000	2·250
Palmitic acid (97% purity)	5·800	6·500
Polyoxyethylene (2) cetyl ether	1·000	1·000
Hydroxyalkyl cellulose (Klucel HA)	0·067	0·075
Carbopol 934	0·180	0·225
Propylene glycol dipelargonate	2·750	2·750
Sorbitol (70% solution)	10·000	10·000
Propylene glycol	3·300	3·300
Triethanolamine	4·200	4·750
Water (deionized)	67·953	66·400
Fragrance, dye	*q.s.*	*q.s.*
n-butane	0·550	0·550
n-pentane	2·200	2·200
Foam stiffness	29·0 g cm^{-2}	69·8 g cm^{-2}

Procedure: Prepare the soap intermediate by adding an aqueous solution of sorbitol and triethanolamine to the fatty acids and polyoxyethylene (2) cetyl ether at 80°C. Add separate solutions of the Klucel HA in aqueous propylene glycol and Carbopol 934 in water to the soap intermediate at 27°C. Disperse the hydrocarbons in an equal volume of propylene glycol at 4°C and mix with the remainder of the formulation in such a way as to avoid trapping air in the gel.

The gel is immediately transferred to the inner compartment of a barrier aerosol dispenser and the valve crimped in place. The outer compartment is pressurized with about 10 ml of a mixture of propane and isobutane having a vapour pressure of approximately 46 psi (317 kPa) at 25°C.

Brushless or Non-lathering Cream

Brushless or non-lathering shaving creams are oil-in-water emulsions. They contain components similar to those in vanishing creams, the main difference being that the concentration of oils and emulsifying agents tends to be higher in the shaving preparations. Ideally, the cream should vanish on completion of the shave, leaving the face free from irritation and with a matt appearance. Since a too rapid disappearance of the cream would be deleterious to the comfort and closeness of the shave, it should be possible at the very least to rub any remaining cream into the skin after the shave.

The popularity of brushless creams is said to be due to their convenience, in that they eliminate the need for a brush and give a faster shave. The thick film of lubricant on the face can provide emolliency and protection to the skin by reducing razor drag during shaving. The lower pH value of brushless creams (7·5–8·5) lends support to the suggestion that they cause less irritation, particularly on broken skin, than lather creams of pH 10. The disadvantages of brushless creams are that more is required per shave than with a foam preparation, the cream is often difficult to rinse from the razor and it can leave the skin feeling greasy. Owing to the slower uptake of water from the emulsion by the hair, the beard-softening action of brushless cream is reported to be less effective than a foam preparation. This may result in a more rapid dulling of the blade edge. To promote beard softening, it is normally recommended that the face is washed with soap and water before applying the cream to the wet face.

Formulation

The oil phase of a typical brushless cream comprises: 4–10 per cent lubricant (for example mineral oil, long-chain fatty acid esters, petrolatum); 10–25 per cent stearic acid to provide a superfatting action and assist the characteristic pearlescent appearance of the cream; and 0–5 per cent emollient (for example lanolin, cholesterol, cetyl alcohol, stearyl alcohol, spermaceti). Spermaceti is widely recommended as a means of preventing the cream from vanishing too rapidly. The aqueous phase usually contains 1–5 per cent soaps (for example potassium or triethanolamine stearate), 0–5 per cent synthetic surfactant to improve emulsion stability, beard wetting and rinsibility (for example glycerol monostearate, sulphonated fatty alcohols, fatty acid amides), 0–1 per cent thickening agent which will also improve emulsion stability (for example gum tragacanth, sodium alginate, polyvinylpyrrolidone, polyacrylic acid and its derivatives), and 2–10 per cent humectant to prevent drying-out of the cream (for example glycerol, sorbitol, propylene glycol). It is normal to add a preservative, for example esters of *p*-hydroxybenzoic acid, to this type of formulation. Other additives, such as perfumes, cooling agents, bacteriostats, etc., as discussed under aerosol shaving foam preparations, can also be included.

The composition of a typical brushless shaving cream is as follows:

	(16) per cent
Mineral oil	9·0
Lanolin	0·5
Stearic acid	14·5
Carbopol 934	0·5
Triethanolamine	2·5
Triethanolamine lauryl sulphate	1·0
Glycerol	5·0
Water	67·0
Preservative, perfume	*q.s.*

Procedure: Heat the oil, lanolin and stearic acid to 75°C. Disperse the Carbopol 934 in cold water and add the glycerol, surfactant and triethanolamine. Add the oil phase to the aqueous phase at 75°C with vigorous stirring. Cool the mixture rapidly, the perfume being added at 45°C.

The composition of a brushless shaving cream quoted in *Seifen-Öle-Fette-Wachse*[36] is given in example 17.

	(17) per cent
Stearic acid	18·0
Lanolin	4·0
Propylene glycol monostearate	4·0
Isopropyl palmitate	4·0
Glycerol	2·0
Triethanolamine	1·0
Water	66·8
Perfume	0·2

The presence of silicone oil in a brushless shaving cream is said to impart a pleasant 'feel' on application and give enhanced razor glide. A formulation given in a *Union Carbide Bulletin*[37] had the following composition:

		(18) per cent
A	Stearic acid	18·0
	Mineral oil	5·0
	Silicone fluid L-45 (1000 cS)	1·0
	Polyoxyethylene (20) sorbitan monostearate	5·0
B	Sorbitol (70% solution)	5·0
	Borax	2·0
	Triethanolamine	1·0
	Water	63·0
	Preservative, perfume	*q.s.*

Procedure: Heat the oil phase to 90°C; heat the aqueous phase separately to 95°C and add to the oil phase with stirring.

Carbowax 1500 may be used in place of oils to formulate so-called non-greasy brushless shave creams:[38]

		(19) parts
A	Carbowax 1500	45·0
	Stearic acid	37·5
B	Triethanolamine	3·0
	Potassium hydroxide	1·6
	Water	2·0
	Sodium alginate	3·5
	Water	178·0
	Propylene glycol	12·0
	Carbitol	15·0
	Perfume	*q.s.*

Procedure: Heat A to 70°C and stir in B. Add the sodium alginate dispersed in water at 70°C followed by the remaining components. The perfume, dissolved in part of the Carbitol, is added when the cream has cooled to 50°C; pour the cream at 45°C.

As with lather shaving creams, the rate of cooling and the amount of stirring can affect the consistency of the product. Cooling the product under vacuum will help to reduce aeration during the manufacture of the cream.

It is possible to obtain a satisfactory brushless shaving cream without using high concentrations of fatty acids. Self-emulsifying glycerol monostearate at a level of 10–25 per cent is a suitable emulsifier for the oils and this produces more translucent creams with better emollient properties than standard creams. An example of this type of cream is as follows:[39]

	(20) per cent
Glycerol monostearate	10·0
Mineral oil	3·0
Lanolin	5·0
Glycerol	3·0
Stearic acid	2·0
Potassium hydroxide	0·1
Water	76·9

Brushless Shaving Stick

Thomas and Whitham[40] describe a brushless shaving stick which can be applied directly to the face. It is claimed that the continuous thin smear left on wetted skin provides adequate lubrication for the shaving operation. The stick is composed of fatty or waxy materials to which hydrophilic properties have been imparted by a suitable emulsifier, for example soap or a partial fatty acid ester of a polyhydric alcohol. This ensures that the product is readily wetted by, but is not more than very sparingly soluble in, water. Pigment, dyestuff or opacifier is incorporated to indicate the presence of the composition on the face.

The following example is quoted:

	(21) *per cent*
Sesame oil	35·35
Spermaceti	45·80
Stearin	7·60
Soap	5·00
Monoglycerides of coconut oil fatty acids	3·00
Titanium dioxide	2·00
Perfume	1·25

Novel Compositions for Wet Shaving

There are a number of products, often referred to as shaving assisting compositions, which function in a slightly different manner from conventional soap-based shaving preparations. These novel compositions place a greater emphasis on the protection of skin during shaving by the provision of an effective layer of lubricant. They are applied directly to the face or to the blade edge and can be used without any other type of wet shaving preparation. Alternatively, they can be considered as a pre-wet shaving preparation.

An example[41] of a composition based on mineral oil is as follows:

	(22) *per cent*
Mineral oil	95·97
Dioctyl sodium sulphosuccinate (Aerosol OT)	1·44
Lanolin	0·96
Silicone fluid (DC 400)	0·67
Octadecanol	0·48
Fragrance	0·48
Preservative	*q.s.*

The preparation is applied to moist (but not wet) skin that has been washed with soap and warm water. The oils and octadecanol provide lubrication and act as a barrier to the evaporation of water, thereby preventing dehydration of the skin and beard hair.

A synergistic action between nonionic and ionic surfactants and silicone fluids is claimed[42] to protect the skin during shaving, facilitate the cutting of the beard and to protect the blade from corrosion between shaves. The compositions can be applied as a lotion or cream and can be used with or without a conventional shaving preparation.

An example of an alcoholic lotion is as follows:

	(23) *per cent*
Methylphenylpolysiloxane (DC-555)	6·6
Dimethylpolysiloxane (DC-200, 350 cS)	6·6
Polyoxyethylene (20) sorbitan monooleate (Tween 80)	6·6
Polyoxyethylene (20) sorbitan monolaurate (Tween 20)	6·6
Dioctyl sodium sulphosuccinate	0·5
Water	25·8
Ethyl alcohol (95%)	47·3

Other preparations make use of the lubricating properties of water-soluble gums and polymers, to which synthetic surfactants, humectants, emollients and oils can be added. Assertions have been made that the anionic soaps and surfactants present in shaving creams tend to emulsify sebum, with the result that the skin is deprived of its natural protection and is left dry, exposed to adverse atmospheric conditions and to the abrading action of the razor blade.

Shaving preparations based on oil-in-water emulsions have been proposed by Clairol.[43] These compositions contains dimethylpolysiloxane (200–500 cS) emulsified with 0·3 to 0·7 per cent polyoxyethylene lauryl ethers in 87–95 per cent water which has been thickened with 0·2–1·0 per cent Carbopol neutralized by triethanolamine to pH 6·5–7·2. The silicone fluid is said to form a protective layer on the skin, thereby preventing the emulsification of sebum, reducing razor drag and minimizing skin irritations.

DRY SHAVING PREPARATIONS

Introduction

It is generally recognized that electric shavers do not cut the beard as close to the skin surface as a razor blade. This was confirmed in a study by Bhaktaviziam *et al.*[44] which also showed that the ends of hair observed 24 hours after shaving with an electric razor showed ragged edges and some vertical splitting of the hair shaft. Both electric and blade shaving result in the removal of skin, the amount removed for an individual being dependent on the pressure applied to the face. Generally, the closer the shave the greater the amount of skin damage. It has been suggested[45] that pre-electric shave preparations may not increase the quality of the shave but may assist in reducing skin damage.

In contrast to blade shaving where it is preferable to soften the beard, when using an electric razor the beard should be dry with individual hairs raised and stiffened so that they can be caught between the razor's combs and removed. The removal of the film of perspiration from the face reduces the friction between the razor and skin and prevents the beard from being slippery and elusive to the cutting edge of the electric razor. This is achieved in different ways by the two most popular forms of pre-electric shave preparation: the lotion, based on an alcoholic solution, and the talc stick. It should be noted that a completely contrary view of the function of a pre-electric shave preparation has been expressed in a patent granted to the Sunbeam Corporation,[46] where it is claimed that the removal of moisture from the skin and beard prior to electric shaving is not desirable: that in fact water softens the beard and by causing hairs to swell and to become elongated ensures a smoother, more efficient and closer shave. Furthermore, alcoholic lotions are claimed to cause shrinking of the hair into the follicle, making it more difficult to obtain a close, clean shave. The preparations claimed in the patent are oil-in-water emulsions containing 5–20 per cent by weight of fatty acid esters such as isopropyl myristate, and an

emulsifying agent which is a mixed alkali metal/amine salt of polyacrylic acid.

Pre-electric Shave Lotion

In formulating a pre-electric shave lotion the following attributes are considered desirable:

(1) Adequate astringency to stiffen the beard and possibly to stimulate the hair follicle muscles.
(2) Quick drying to allow rapid evaporation of any moisture present on the face.
(3) A pH below the iso-electric point of keratin to prevent swelling of the hair (that is, pH 4·5–4·8).
(4) Provision of a coating on the skin on which the razor will glide, thereby preventing irritation of the skin and providing lubrication for the cutting edge of the electric razor.
(5) Freedom from any substances likely to corrode the cutting head.
(6) Absence of any lubricants likely to have an adverse effect on plastic components of the electric shaver.

The alcoholic pre-electric shave lotions may be either astringent or oily. The astringent lotions are intended primarily to dry and stiffen the hairs and, theoretically at least, to assist in raising them. The astringent effect of the alcohol can be further enhanced by the inclusion in the preparation of mildly astringent substances such as aluminium chlorhydroxide, zinc phenolsulphonate or lactic acid. Menthol or camphor may be included to give a cooling effect together with a suitable antiseptic and a low level of lignocaine as an analgesic. Compounds having pilomotor activity may also be added to pre-electric shave preparations.

Lotions of the oily type aim to deposit on the face a film of lubricant which reduces the drag of the cutting head against the skin. It has been shown[7] that a film of silicone oil substantially reduces the frictional force between skin and a smooth steel probe. The mechanism involved is hydrodynamic lubrication—that is, the frictional force is dependent on the viscosity of the lubricant. Perhaps the most frequently used lubricants for this type of product are the esters of higher fatty acids such as isopropyl myristate. By suitable choice of lubricant type and concentration, it should be possible to provide for a comfortable shave even in warm humid conditions without leaving the skin feeling oily. It is claimed by some that the oily type of preparation lengthens the life of the cutting edge of the electric razor because of its lubricating action.

Example Formulations

Astringent pre-electric shave lotions

	(24) *per cent*
Ethanol	45·0
Sorbitol	5·0
Lactic acid	1·0
Water	49·0

	(25) *per cent*
Zinc phenolsulphonate	1·0
Distilled extract of witch hazel	40·0
Ethanol	40·0
Water	18·8
Menthol	0·1
Camphor	0·1

	(26) *per cent*
Aluminium chlorhydroxide (50%)	5·0
Isopropyl myristate	5·0
Ethanol	80·0
Perfume	*q.s.*
Colour	*q.s.*
Water	to 100·0

Lubricant pre-electric shave lotions

	(27) *per cent*
Isopropyl myristate	20·0
Ethanol	80·0
Perfume	*q.s.*
Antiseptic	*q.s.*

	(28) *per cent*
Ethanol	77·0
Isopropyl myristate	13·0
Oleyl alcohol (cosmetic grade)	4·0
Perfume	1·0
Distilled water	5·0
Colour	*q.s.*

A pre-electric shave lotion containing a pilomotor agent was quoted in a patent assigned to E. Merck A–G.[20] It had the following composition:

	(29) *per cent*
2-(2',5'-dimethoxybenzyl)-2-imidazoline	0·1
Citric acid	2·5
Polyvinyl pyrrolidone	0·5
Isopropyl myristate	3·5
Alcohol (96%)	80·0
Perfume	*q.s.*
Water	to 100·0

Pre-electric shave lotions may be applied directly to the face by a roll-on type of applicator. In such circumstances it may be necessary to adjust the viscosity and wetting properties of the lotion to prevent seepage round the ball when the applicator is inverted.

Collapsible Foam Pre-electric Shave Lotion

To aid the transference of the pre-electric shave lotion from the hand to the face, quick-breaking aerosol foams have been developed. The foam is quite stable and confined to a limited area as dispensed, but breaks to a thin liquid when sheared or warmed by body heat. The foam concentrate typically contains 55–70 per cent of an aqueous ethanol solution, 4–10 per cent of a lubricant, 0·5–5 per cent of a surfactant which should be soluble in only one of the miscible solvents but form a clear homogeneous solution on addition of 3–10 per cent of a liquefiable propellant to the concentrate. The persistence of the foam when left undisturbed on the hand can be varied from a few seconds to several minutes depending on the proportions of alcohol, water and propellant and the type and concentration of surfactant. The mechanism of foam stabilization is complex but appears to rely on the partial insolubilization and loose molecular structure formation by the surfactant in the aqueous ethanol solution once the propellant has evaporated. The foam collapses on shearing because the bubble walls are extremely thin compared with those of soap-based aerosol shaving foams.

The surfactants found to be suitable for most quick-breaking aerosol foams are nonionic emulsifiable waxes composed of polyethylene glycol ethers of cetyl and stearyl alcohol and auxiliary emulsifying agents, for example Polawax A-31 (Croda Chemicals Ltd), Promulgen Types D and G (Robinson Wagner Co.). The addition of lubricant oils to the concentrate can cause problems of instability; however, a limited number of compounds have been shown[47] to possess the right combination of dry lubricity, solubility in aqueous ethanol solutions and initial foam stability. Examples include di-isopropyladipate, dimethyl sebacate, diethyl succinate and propylene carbonate.

The composition of a collapsible foam pre-electric shave lotion disclosed in a patent assigned to Yardley[47] was as follows:

	(30) *per cent*
Di-(2-methoxy-2-ethoxy)ethyl adipate	2·4
Denatured ethyl alcohol (95%)	68·1
Polawax A-31	4·9
Water	21·9
Isobutane	2·7

Pre-electric Shave Gel Stick

Solid pre-electric shave sticks of the cologne type can be formed by gelling ethanol with sodium stearate in the presence of glycerol and a suitable lubricant.

Pre-electric Shave Talc Stick

Talc is used as the main component in some pre-electric shave preparations to absorb perspiration and sebaceous secretions from the skin and to confer its characteristic slip so that the head of the shaver will glide smoothly over the face. A reduction of 50 per cent in the frictional force between skin and polished steel was observed[7] after treating the skin with talc. Colloidal kaolin is usually present

in the preparation to improve the moisture-absorbing capacity and adhesion to the skin. Zinc or magnesium stearate is included to enhance both adhesion and slip. Magnesium carbonate or precipitated chalk serves as the carrier for the perfume as well as increasing the absorbent properties. An important stipulation is that powders for pre-electric shave purposes should be free from grit to avoid abrading the cutting edge of the electric razor. This can be achieved by grinding the powders before use.

The most convenient way to apply the talc preparation to the face is to form it into sticks. The sticks can be moulded from an aqueous dispersion of the powders using colloidal magnesium aluminium silicate (Veegum) as the binder.

A formula for a pre-shave talc stick was given in a Technical Bulletin of the R.T. Vanderbilt Co. Inc.[48] It had the following composition:

		(31) *parts*
A	Veegum	1·9
	Water	30·0
B	Zinc stearate	4·7
	Light magnesium carbonate	1·9
	Perfume	*q.s.*
	Talc	91·5

Procedure: Add the Veegum slowly to water with continuous agitation to produce a smooth dispersion. Absorb the perfume with the magnesium carbonate, add the zinc stearate and disperse them in the talc. Add A to the powder blend B and mix to a smooth paste. Pour into moulds and allow to dry until hard. The sticks are finally dried in an oven.

It is claimed that the resulting sticks do not break easily and that they have excellent rub-off qualities. The degree of rub-off and the strength of the stick can be controlled by the level of the binder.

A method for the manufacture of talc sticks without the use of a binder in the talc was disclosed in a US patent[49] which quoted the following formula:

	(32) *per cent*
Talc	50
Zinc oxide	10
Chalk	10
Kaolin	10
Colloidal silica	20

The sticks are formed by compression moulding the powder mixture at pressures ranging between 450 and 600 psi (3–4 MPa), then coating, except on the end, with a suitable film-forming polymer to protect them against cracking or crumbling.

Pre-electric Shave Powder

A loose powder which can be used as a pre-electric shave preparation is illustrated by example 33.

	(33) per cent
Talc	50·0
Kaolin	14·0
Magnesium carbonate	12·0
ANM powder (etherified starch)	10·0
Cetyl alcohol	3·0
Glycerol monostearate	1·0
Zinc stearate	4·0
Zinc oxide	5·5
Perfume	0·5

To overcome the problems of handling the powder and to avoid spillage, pre-electric shave powders have been packed in aerosol containers. A low-pressure propellant mixture and careful selection of actuator are required to produce a soft, dry spray which does not result in excessive 'bounce' of fine particles from the target surface.

Zinc oxide, zinc stearate, kaolin and calcium carbonate all tend to agglomerate in the presence of propellant and cannot be used in powder aerosols. Minor portions of colloidal silica (Aerosil), magnesium carbonate, magnesium stearate and starch can be used to improve the dispersion of talc in the propellants. Isopropyl myristate or mineral oil (0·5–1 per cent) can be used as a lubricant and also to aid dispersion. The total powder content of these compositions rarely exceeds 15 per cent of the total weight in order to avoid blockage of the valve or actuator.

Example 34[50] illustrates the possible composition of a pre-shave powder aerosol:

	(34) per cent
Talc	80·0
Aerosil	5·0
Starch	4·5
Magnesium stearate	5·0
Light magnesium carbonate	5·0
Perfume	0·5

This powder base is passed through a 200 mesh sieve and packed into aerosol containers as follows:

	per cent
Powder base	15
Propellant 11	60
Propellant 12	25

AFTER-SHAVE PREPARATIONS

Wet or dry shaving causes the removal of skin as well as hair from the face. The total quantity of skin and hair removed can vary by a factor of 4 or more, depending on the individual. Similarly, the percentage of skin in the shaving

debris can range between 25 and 75 per cent.[1] Much of the skin removed is the epidermal horny layer which would be shed naturally without shaving. The skin trauma associated with shaving occurs when the outer horny layer is penetrated. Damage is most likely to occur at follicular hairshaft openings.[1] A second source of irritancy in shaving is from the shaving preparation. The degreasing effect of soaps and synthetic surfactants can increase skin permeability and allow alkali and other irritants to reach the Malpighian cells.[51]

The purpose of an after-shave preparation is to relieve the slight irritation or 'after-glow' and confer a pleasant feeling of comfort and well-being after shaving. This is achieved by giving a slight coolness, anaesthesia, mild astringency or emolliency to the skin. At the same time, the preparation should be antiseptic and help to keep the skin free from bacterial infection during the short time it takes to recover from the slight degree of injury inflicted during the shaving operation. The extent to which these properties are emphasized depends on the type of formulation. The materials used in after-shave preparations will be discussed principally in the context of lotions.

After-shave Lotion

In its simplest form, an after-shave lotion is a clear aqueous ethyl alcohol solution containing a perfume. The desired balance of mild astringency and coolness is achieved by controlling the ratio of ethyl alcohol to water. Analysis of popular UK brands of after-shave lotion shows that they contain 50–70 per cent by weight ethyl alcohol. Other countries, notably Germany because of the tax structure, use much lower concentrations of alcohol. US sources recommend 40–60 per cent by volume of alcohol to obtain the balance of properties; however, manufacturers of popular brands tend to use alcohol levels similar to those in the UK.

The commercial success of an after-shave lotion is largely dependent on the perfume and the way in which the product is marketed. Many different perfume types, for example spicy, chypre, sandalwood, leather and tobacco, have been successful. The creation of a stable balanced perfume, which is free from components likely to cause skin irritation or sensitization, is the province of the perfumer.

The chemical composition of the perfume determines the maximum concentration at which it can be used in a particular water–alcohol mixture. It may be necessary with some perfumes to increase the alcohol content in order to achieve the required perfume level. In a situation where it is undesirable to increase the alcohol content or reduce the fragrance level, it is common practice to use a solubilizer to obtain a clear lotion. Nonionic surfactants with a hydrophile–lipophile balance (HLB) number in the range 15–18 are often found to be the most effective solubilizers, although anionic surfactants have also been used. For more detailed information, reference should be made to published work[52–54] on the effectiveness of surfactants in solubilizing specific perfume oils. The solubilization of a perfume does not appear to reduce its stability or to cause a deterioration in the odour.[52] Sugar-based surfactants, for example sucrose esters, sucroglycerides and ethoxylated sucroglycerides may make useful perfume solubilizers in after-shave lotions since they are said[55] to cause less

defatting of the lipid layer than the more usual polyoxyethylene derivatives of fatty acids and alcohols and are therefore less likely to cause skin irritation.

A perfume oil containing resins, terpenes and certain crystalline materials is more difficult to solubilize and may require several times as much surfactant as perfume oil. A perfume based on terpeneless oils, alcohols, compounds of low molecular weight and polar compounds will require less surfactant. The type and level of solubilizer required is determined by dissolving the perfume and surfactant in alcohol and titrating with water to the required alcohol/water ratio. The optimum level of surfactant is that which just gives a clear micellar solution that remains stable over an appropriate range of temperatures (0°–40°C).

Humectants and emollients are frequently added to after-shave lotions at levels not exceeding 5 per cent. Polyols such as glycerol, sorbitol and propylene glycol help to maintain the water content of the skin. Glycerol has the best humectant properties of the group, but propylene glycol is often preferred because of its greater solvent power, lower viscosity and higher volatility. The feel of the skin can be improved by the addition of long-chain fatty esters, for example isopropyl myristate or lanolin. Quantities are often limited by their low solubility in aqueous alcohol solutions. Water-soluble lanolin derivatives can be used at higher levels to provide emolliency and to assist in the solubilization of the perfume oil.

Cooling of the skin results from the evaporation of the alcoholic solution. The effect can be augmented by the physiological cooling effect of menthol. The level of menthol should be kept below 0·1 per cent because of its lachrymatory properties and because its odour can upset the balance of the perfume. Odourless cooling agents[19] may be more appropriate for this type of product. Menthol is also said to cause slight surface anaesthesia of skin; however, it is preferable to achieve this effect with lignocaine at a level of 0·025–0·05 per cent.

The mild astringency of the alcohol can be supplemented by witch hazel extract or even zinc and aluminium compounds such as zinc phenolsulphonate, aluminium chlorhydroxide or alcohol-soluble aluminium chloride complexes.

In a study of the effects of after-shave lotions on skin flora, Theile and Pease[56] showed that an aqueous solution containing 55 per cent by weight ethyl alcohol reduced the facial flora count by over 90 per cent immediately after application, the count returning to the pre-application level after six hours. With the same alcoholic solution containing a perfume, the skin flora count was again reduced by over 90 per cent immediately after application and was still 35 per cent below the pre-application level after six hours. This accords with the well-established antimicrobial activity of many perfume oils. Although alcoholic solutions reduce facial flora, tests *in vitro* demonstrate that they are unable to inhibit the growth of bacteria and fungi on agar plates. Some inhibitory action is found with fragranced alcoholic solutions, but a much greater effect can be achieved with quaternary ammonium compounds. The addition of 0·1 per cent benzalkonium chloride to an after-shave lotion was found to double the zone of inhibition of facial bacteria growth.

Cationic surfactants are wide-spectrum germicides which can kill or inhibit growth of organisms over a wide pH range. Quaternary ammonium compounds, for example cetyl trimethyl ammonium bromide, can be used in after-shave preparations provided that anionic surfactants have been used to solubilize the

perfume. Anionic surfactants have some activity against Gram-positive and yeast organisms but are rarely effective against Gram-negative bacteria. Nonionic surfactants are not considered to be germicidal. However, a significant development is the finding that monoesters formed from polyhydric alcohols and lauric acid (Lauricidin) have germicidal activity and they are GRAS materials.[57] This offers the possibility of perfume solubilization and germicidal activity in a single compound. More powerful bacteriocides and fungicides are available but these would require careful evaluation to ensure compatibility with the lotion and freedom from skin irritation or sensitization.

Soap-based shaving preparations tend to leave the skin slightly alkaline, whereas the pH value of normal skin is 5 to 6. Formerly it was suggested that boric acid was a useful component in after-shave lotions, both as an antiseptic material and as a neutralizer of any residual alkalinity. There is a slight possibility of boric acid intoxication by absorption through damaged skin and therefore it is preferable to use lactic or benzoic acid.

Allantoin is frequently added to after-shave lotions at a level of 0·1–0·2 per cent to promote wound healing.

Example Formulations

A basic after-shave lotion, not requiring solubilization of the fragrance, can be made up as in example 35.

	(35) *per cent*
Ethyl alcohol, specially denatured	60
Propylene glycol	3
Water, demineralized	36
Perfume	1

Procedure: Dissolve the perfume and propylene glycol in the alcohol and add the water slowly, stirring well to avoid locally high concentrations of water precipitating the less soluble components of the perfume. Allow the solution to stand for several hours at about 4°C, then filter.

Antiseptic after-shave lotion[58]	(36) *per cent*
Hyamine 10-X (25%)	0·250
Ethyl alcohol	40·000
Menthol	0·005
Benzocaine	0·025
Water	59·720
Perfume	*q.s.*

Astringent after-shave lotion	(37) *per cent*
Witch hazel extract	15·00
Ethyl alcohol	10·00
Alum	0·50
Menthol	0·05
Ethyl *p*-amino benzoate	0·05
Glycerol	5·00
Water	69·40

An aerosol after-shave lotion (example 38) is given in a Technical Bulletin[59] by Esso Chemicals.

	(38) *per cent*
Hexadecyl alcohol	0·8
Ethyl alcohol	53·7
Distilled water	33·0
Polawax A-31	2·0
Perfume	0·5
Propellant 12/114 (40:60)	10·0

A formulation containing colloidal alumina[60] gives a cooling astringent lotion with excellent lubricity:

		(39) *per cent*
A	Baymal alumina	2·10
	Water	57·90
B	Alcohol (74 OP)	36·950
	Polyethylene glycol (400) distearate	3·000
	Menthol	0·025
	Camphor	0·025
	Preservative, perfume	*q.s.*

Procedure: Parts A and B are prepared separately using heat as required to dissolve the PEG distearate in the alcohol. The two parts are mixed cold.

Some components of perfumes are notorious for their instability when exposed to ultraviolet light. It is not unusual to find that, after exposure to direct sunlight for a few months, an after-shave lotion in clear glass bottles develops a characteristic 'bottle-odour', quite unlike the original fragrance. Accelerated testing of the ultraviolet light stability of the packaged product should therefore be included in the evaluation of after-shave preparations. Many manufacturers circumvent the problem by using opaque or chromium-containing glass bottles to package the lotion.

Quick-break Foam After-shave

To aid the transference of the after-shave lotion from the hand to the face, quick-breaking aerosol foams have been developed. The principles of the action of this type of product have been discussed in the section on collapsible foam pre-electric shave lotion.

A quick-breaking after-shave lotion from the General Chemical Division of Allied Chemical[61] is given in example 40.

		(40) *per cent*
A	Polawax A-31	1·50
	Ethyl alcohol (SDA No. 40)	62·10
B	Menthol	0·05
	Camphor	0·05
	Perfume	0·30
C	Emcol E-607	0·20
	Allantoin	0·10
	Water (distilled)	35·70
	Concentrate	92
	Propellants 12/114 (20:80)	8

Procedure: Warm part A to 45°C to dissolve the Polawax; cool to 37°C and add part B. Heat part C to 80°C to dissolve the components; cool to 37°C and add to the solution of A and B. Fill while still warm.

Crackling Foam Aerosol After-shave Lotion

After-shave preparations have been formulated that are dispensed from an aerosol container as a foam and which exhibit a crackling sound when subjected to shear during application to the face. Compositions of this type are said to be oil-in-water emulsions, the continuous aqueous phase containing suitable emulsifiers and the oil phase consisting of the liquefied propellant and propellant-soluble materials. The propellant, a fluorochlorocarbon, constitutes 75–95 per cent by weight of the emulsion.

An example[62] of a crackling aerosol after-shave lotion is as follows:

	(41) *per cent*
Di-isopropyl adipate	0·778
Perfume	1·090
Menthol	0·060
Tergitol-XD*	0·500
Water	9·572
Propellant 114	88·000

* Monobutoxy ether of polyethylene-polypropylene glycols mol. wt 2500 (Union Carbide).

Procedure: Blend the first three components and stir the resulting mixture into water containing Tergitol-XD. Cool this emulsion to 1°C and add 17·6 parts by weight of Propellant 114, pre-chilled to 1°C. Stir the resulting mixture until a uniform emulsion is formed, when the balance of the Propellant 114 (70·4 parts by weight) can be added. The resulting mixture is placed in pre-chilled (1°C) aerosol containers and the valve is crimped in place.

After-shave Gel

An aqueous alcoholic gel can be formed by neutralizing a carboxyvinyl polymer with a base. The amount of gelling agent (usually less than 1 per cent) and the degree of neutralization controls the stiffness of the gel. The gel may optionally contain a physiological cooling agent and an emollient which is soluble in the alcoholic solution.

Example 42 gives an after-shave gel from a B.F. Goodrich Chemical Co. Bulletin.[63]

	(42) per cent
Ethanol	45·1
Water	53·0
Carbopol 940	1·0
Menthol	0·1
Di-isopropylamine	0·8
Perfume oil	*q.s.*

Procedure: Dissolve the perfume and menthol in the alcohol and then slowly stir in most of the water (a solubilizer can be used to obtain a clear solution). Disperse the Carbopol 940 in the aqueous alcoholic solution. Reduce the speed of the mixer and slowly add the di-isopropylamine dissolved in the small quantity of retained water.

The resulting product should be a crystal-clear gel, which is subject to degradation by ultraviolet light. It is preferable, therefore, to package it in coloured or opaque containers. Alternatively, UV stabilizers can be added to the formulation.

A similar formulation,[64] containing Viscofas X 100 000 (1 per cent) neutralized by tri-isopropylamine (0·1 per cent) in place of Carbopol and di-isopropylamine, can be prepared by dispersing the Viscofas in water at 90°C, allowing it to cool to room temperature before adding the alcohol and then the tri-isopropylamine.

Salts of glycyrrhizic acid, derived from licorice roots, can be used to form transparent gels at pH values from 2 to 6. The strength of the gel can be increased by the addition of water-soluble metal salts, for example zinc sulphate, alum, zinc phenolsulphonate.

Astringent after-shave gel[65]	(43) per cent
Dipotassium glycyrrhizinate	1·0
Citric acid	0·5
Zinc sulphate	0·2
Zinc phenolsulphonate	0·2
Ethyl alcohol	10·0
Propylene glycol	5·0
Water	83·1
Perfume, preservative	*q.s.*

Procedure: A mixture of dipotassium glycyrrhizinate, alcohol and propylene glycol is prepared and the perfume added. Heat this mixture to about 50°C and add an aqueous solution of citric acid, the zinc salts and preservative. The resulting solution is cooled to around 10°C and allowed to stand overnight.

After-shave Cream and Balm

The astringency of after-shave preparations containing more than 50 per cent by weight alcohol can be irritating to skin which has been excessively damaged by shaving or over-exposure to sun and wind. Increasingly, manufacturers are introducing creams or balms into their range of after-shave preparations. The formulations used to obtain the soft-textured, oil-in-water emulsions are often similar to vanishing or moisturizing creams. There is some advantage to be gained from using soap-free compositions in that the pH of the emulsion can be adjusted to the slightly acid value of normal skin.

	Soap-free after-shave cream[66]	(44) per cent
A	Glycerol monostearate S/E (Teginacid H)	10·0
	Mineral oil	10·0
	Petrolatum	6·0
	Tegiloxan 100	0·5
	Lanolin	3·0
	Cetyl alcohol	3·0
B	Glycerol	3·0
	Citric acid	0·2
	Potassium aluminium sulphate	0·1
	Water	64·2
	Perfume	*q.s.*

	Opaque hydro-alcoholic balm[67]	(45) per cent
A	Amerchol L-101	5·0
	Isopropyl lanolate	1·0
	Polyethylene glycol (1540) monostearate	3·0
B	Carbopol 934	0·5
	Water	60·0
	Triethanolamine	0·5
	Ethyl alcohol	30·0
	Perfume	*q.s.*

Procedure: Add the Carbopol 934 slowly to the water at room temperature with rapid agitation. Mix thoroughly until a thin cloudy dispersion is obtained. Heat the Carbopol solution and the oil phase A separately to 75°C. Add the Carbopol solution to the oil phase and stir for 5 minutes to emulsify before adding the triethanolamine. Cool with stirring to 38°C. Add the alcohol and perfume and continue cooling.

After-shave Powder

The main purpose of after-shave powders, as of all other after-shave preparations, is to alleviate any discomfort produced by shaving and leave the face cool and refreshed. Additional possible functions of an after-shave powder are to cover minor skin defects and to mask any unacceptable shine produced by an excessively oily brushless shaving cream, leaving the face with a smooth matt appearance. Further functions can be added if desired, for example, the cooling effect produced by menthol, mild astringency by the incorporation of an aluminium salt, antimicrobial activity, agents to sooth irritation and to promote healing of minor wounds.

The important properties of an after-shave powder are slip, adherence and absorbency. Covering power is less important in after-shave powders than in the closely related face powder compositions. The main component of an after-shave powder is talc which provides slip and absorbency. Absorbency can be improved by the presence of kaolin or magnesium carbonate, while covering power is provided by precipitated chalk, zinc oxide or titanium dioxide. Colour is obtained from cosmetic-grade pigments. An ochre will produce a light tan effect, whereas an iron oxide will give a light pink colour. A mixture of these two pigments will produce a tone which will make the powder less conspicuous on the average Caucasian skin. Such a powder must adhere well to skin and so metallic soaps, for example zinc stearate, are usually added to the formulation.

The method of manufacture is very similar to that of face powders and talcum powders. Control of particle size is important and if necessary mixing should be preceded by a grinding process. Powder-grade perfumes should be absorbed by precipitated chalk before incorporation into the powder mix.

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Administration Order 7400.9K, Airspace Designations and Reporting Points, dated August 30, 2002, and effective September 16, 2002, is amended as follows:

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

ASO MS E2 Elizabeth City, NC [Corrected]

Elizabeth City CGAS/Regional Airport, NC
(Lat. 36°15'38" long. 76°10'29")

That airspace extending upward from the surface within a 4.1-mile radius of the Elizabeth City CGAS/Regional Airport.

* * * * *

Issued in College Park, Georgia, May 28, 2003.

Walter R. Cochran,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 03-14071 Filed 6-3-03; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 347, and 352

[Docket Nos. 78N-0021 and 78N-021P]

RIN 0910-AA01

Skin Protectant Drug Products for Ov r-the-Counter Human Use; Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule in the form of a final monograph establishing conditions under which over-the-counter (OTC) skin protectant drug products are generally recognized as safe and effective and not misbranded as part of the ongoing review of OTC drug products conducted by FDA. The final monograph includes OTC skin protectant drug products for minor cuts, scrapes, burns, chapped skin and lips, poison ivy, poison oak, poison sumac, and insect bites. FDA is issuing this final rule after considering public comments on the agency's proposed regulation, which was issued in the form of a tentative final monograph, and all new data and information on skin protectant drug products for these specific uses that have come to the agency's attention. This final rule amends the regulation that lists nonmonograph active ingredients by adding those OTC skin protectant ingredients that have been found to be not generally recognized as safe and effective. This final rule also lifts the stay of 21 CFR part 352 (published at 66 FR 67485, December 31, 2001) to amend the final monograph for OTC sunscreen drug products to include sunscreen-skin protectant combination drug products, and then stays § 347.20(d) (21 CFR 347.20(d)) and part 352 until further notice in the **Federal Register**.

DATES: *Effective Date*: This rule is effective June 4, 2004.

Compliance Dates: The compliance date for products subject to parts 310 and 347 (21 CFR parts 310 and 347) with annual sales less than $25,000 is June 6, 2005. The compliance date for all other products subject to parts 310 and 347 is June 4, 2004. The compliance date for combination products containing skin protectant and sunscreen active ingredients in § 347.20(d) and for all products subject to part 352 is stayed until further notice.

Comment Date: Submit written or electronic comments on specific labeling items discussed in section X of the **SUPPLEMENTARY INFORMATION** section of this document by September 2, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 4, 1978 (43 FR 34628), FDA published an advance notice of proposed rulemaking to establish a monograph for OTC skin protectant drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class (§ 330.10(a)(6) (21 CFR 330.10(a)(6))).

In the **Federal Register** of February 15, 1983 (48 FR 6820), FDA published the proposed regulation for OTC skin protectant drug products in the form of a tentative final monograph (TFM). In the **Federal Register** of October 3, 1989 (54 FR 40808), the agency published a document to amend the TFM to include OTC drug products for poison ivy, oak, and sumac and for the treatment and/or neutralization of insect bites. This final rule completes the TFMs published on February 15, 1983, and October 3, 1989, amends the final monograph for OTC skin protectant drug products used as astringents in part 347 published on October 21, 1993 (58 FR 54458), and incorporates the name change ("witch hazel") published in the **Federal Register** of June 3, 1994 (59 FR 28767).

In the **Federal Register** of May 10, 1993 (58 FR 27636), the agency issued a final rule establishing that certain active ingredients, including some skin protectant active ingredients, in OTC drug products are not generally recognized as safe and effective or are misbranded. These skin protectant ingredients are listed in § 310.545(a)(18). This final rule adds several ingredients to that section.

On or after 12 months after date of publication in the **Federal Register**, and 24 months after date of publication in the **Federal Register**, for products with annual sales less than $25,000, except combination products containing skin protectant and sunscreen active ingredients, and for combination products containing skin protectant and sunscreen active ingredients, no OTC drug product that is subject to this final rule and that contains a nonmonograph condition may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved new drug application or abbreviated new drug application. Further, any OTC drug product subject to this final rule that is repackaged or relabeled after the effective dates of the final rule must be in compliance with the monographs regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily as soon as possible.

All "OTC Volumes" cited throughout this document refer to information on public display in the Dockets Management Branch (*see* **ADDRESSES**).

II. The Agency's Conclusions on the Comments

(Comment 1) One comment stated its continuing position that OTC drug monographs are interpretive, as opposed to substantive, regulations.

The agency addressed this issue and reaffirms its conclusions stated in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products (37 FR 9464 at 9471 to 9472, May 11, 1972); in paragraph 3 of the preamble to the TFM for OTC antacid drug products (38

FR 31260, November 12, 1973); and in paragraph 1 of section I of the preamble to the TFM in the present proceeding (48 FR 6820 at 6821).

(Comment 2) One comment requested that the definition of "skin protectant" be reworded to add a primary effect of skin protectants, i.e., temporary relief of the effects of harmful or annoying stimuli and to include the word "product". The agency agrees and is revising the definition of "skin protectant" in § 347.3(d).

(Comment 3) Four comments opposed the agency's "exclusivity policy," which limits the indications used in OTC drug product labeling to the "specific words and phrases" approved by FDA in a final OTC drug monograph.

After these comments were submitted, the agency published a final rule in the **Federal Register** of May 1, 1986 (51 FR 16258) changing its labeling policy (§ 330.1(c)(2) (21 CFR 330.1(c)(2))) for stating the indications for use of OTC drug products. That policy was revised and discussed in the **Federal Register** of March 17, 1999 (64 FR 13254 at 13270 to 13271, and 13294). The final rule in this document is subject to that new labeling policy.

(Comment 4) Three comments disagreed with the agency's position of prohibiting cosmetic claims from appearing in any portion of the labeling that is required by an OTC drug monograph and the agency's view that this type of labeling could be misleading (*see* 48 FR 6820 at 6823). One comment noted its support for the distinction made by the agency between "drug" and "cosmetic" claims for the same ingredient. Two comments cited current agency regulations in § 701.3(d) (21 CFR 701.3(d)) regarding the combined label declarations of active drug ingredients and cosmetic ingredients and requested that cosmetic indications be allowed to be stated in a manner that is not false or misleading, without regard to their position on the label.

The agency has revised its labeling requirements for OTC drug products by adding § 201.66 (21 CFR 201.66) and amending § 701.3(d) since stating its position on drug-cosmetic labeling in the TFM. Section 701.3(d) now requires separate listing of the active drug ingredients and the cosmetic ingredients where a cosmetic product is also an OTC drug product. FDA does not review and approve cosmetic terminology in OTC drug monographs. Under the new OTC drug product labeling format in § 201.66, the "Drug Facts" area of a product's labeling only contains the indication(s) for the drug part of the product. Thus, manufacturers are not allowed to commingle drug and cosmetic claims within this specific area of the labeling. However, there are no specific restrictions on commingled information outside of the "Drug Facts" area of a product's labeling. The agency's position is that if commingled drug and cosmetic labeling information is confusing or misleading, the product's labeling may be misleading within the meaning of the Federal Food, Drug, and Cosmetic Act (the act) and the product misbranded under sections 502(a) or 602(a) of the act (21 U.S.C. 352(a) or 362(a)). The agency will review the labeling of affected products on a case-by-case basis.

(Comment 5) Several comments suggested that limiting the statement of identity to one term ("skin protectant") is too restrictive, requested other equally descriptive appropriate terms, and asked for distinct statements of identity for each indication proposed in the monograph, e.g., "minor cut protectant."

The agency does not find it necessary to have distinct statements of identity for each use of a skin protectant drug product. The statement of identity is intended to provide information on the "general pharmacological category(ies) of the drug or the principal intended action(s) of the drug" (*see* § 201.61(b) (21 CFR 201.61(b))). This position is consistent with the statement of identity proposed by the agency as "external analgesic" for all drug products that provide relief of pain and itching caused by a number of conditions (48 FR 5852 at 5868, February 8, 1983) and as "analgesic (pain reliever)" for all drug products that relieve pain due to various conditions (53 FR 46204 at 46211, November 16, 1988).

The agency concurs with one comment's suggestion of adding the dosage form to the statement of identity, i.e., "skin protectant (dosage form)." The *United States Pharmacopeia* (*USP*) lists a number of dosage forms that might be used for OTC topical drug products (Ref. 1). From a marketplace survey (Refs. 2, 3, and 4), the agency finds that the most widely used dosage forms for OTC skin protectant drug products are lotions, creams, ointments, and gels. The examples of dosage forms listed in the statement of identity in § 347.50(a) of this final monograph are not all inclusive and depend on products' historical marketing as skin protectants.

(Comment 6) One comment questioned the agency's statement that the term "soothes" is a cosmetic claim in the context of skin protectant products (48 FR 6820 at 6828).

The agency considers claims such as "temporarily protects" and "helps relieve" to be more informative than "soothes" in conveying to consumers that a drug product provides therapeutic action. The term "soothes" may appear elsewhere in the product's labeling.

(Comment 7) Several comments contended that the indications proposed were too restrictive and omitted indications recommended by the Panel. The comments suggested additional labeling claims.

The agency agrees with some of the comments' suggestions for the indications in § 347.50(b)(2). While the agency wishes to emphasize the "protectant" function of these ingredients, they may also help provide some relief for chapped or cracked skin and lips. Therefore, the agency is allowing manufacturers to add, at their option, the words "and helps relieve" after the word "protects" in the indications in § 347.50(b)(2). The agency also agrees that the words "cold" and "wind" are informative to consumers, and possibly easier to understand than the word "windburned." Accordingly, the agency has made this revision in an optional labeling statement.

The agency considers other suggested claims to be better represented in the agency's proposed indications.

The agency is deleting "sunburn" from the indication proposed in § 347.50(b)(1) because the agency has reexamined the data and determined that they do not support a "protection of sunburn" claim for these ingredients. The "sunburn" claim proposed in the TFM originated from the Panel when it recommended the use of "skin protectant active ingredients for symptoms of dryness: 'For symptoms of chapping, peeling or scaling' (optional, any or all of the following) 'due to minor burns, sunburn, windburn, scrapes, abrasions, or cracked lips'" (*see* 43 FR 34628 at 34648). The Panel also recommended that the ingredients allantoin, cocoa butter, dimethicone, glycerin, petrolatum, and shark liver oil be included in the monograph as active ingredients for symptoms of dryness. Of these ingredients, petrolatum was the only one that the Panel discussed effectiveness for sunburn (43 FR 34628 at 34639). The Panel stated that "the use of petrolatum as an emollient has been well accepted for dry skin conditions, especially with flaking skin such as sunburn, and chapping" (43 FR 34628 at 34639).

The Panel's claim was revised in the TFM to a shortened "drug" claim that stated: "For the temporary protection of minor cuts, scrapes, burns, and sunburn" (*see* 48 FR 6820 at 6832). The agency did not include peeling or scaling claims in the TFM (48 FR 6820

at 6828). The Panel's reference to symptoms of dryness was not included in the TFM because the agency considers the use of skin protectants for dryness to be a cosmetic claim. The agency has now determined that it should not have included the "sunburn" claim in the TFM because the only context in which the Panel discussed it was cosmetic in nature.

The agency is also concerned that skin protectants may inappropriately be used for "sunburn" because the data indicate that it is not desirable to apply a skin protectant to sunburn that has just occurred. As the Panel noted, when petrolatum is applied to sunburn, evaporation is curtailed (43 FR 34628 at 34639). The agency is concerned that application of skin protectants, such as petrolatum and the other igredients for which the Panel recommended a dryness claim for sunburn, to sunburn that has just occurred would occlude the area and prevent evaporation from occurring or significantly reduce evaporation. Thus, there are no data in the administrative record for this rulemaking to support a "protection of sunburn" claim for these ingredients. The agency would consider including such a claim for these ingredients, however, if adequate supporting data are provided.

The agency has determined that insufficient data were submitted to include the words "to allow healing to begin" and to include uses for heat rash, burning feet, and foot discomfort in § 347.50(b)(3). The agency concludes that the expanded "uses" section in this final monograph provides manufacturers an adequate number of options for labeling OTC skin protectant drug products.

(Comment 8) One comment mentioned that no wound healing claim or Category I labeling was provided for three skin protectant ingredients: Allantoin, live yeast cell derivative (LYCD), and zinc acetate.

The Panel classified these ingredients as Category III skin protectants for wound-healing based on the lack of effectiveness data (43 FR 34628 at 34644 through 34647). Insufficient data were submitted for LYCD (*see* section II. comment 25 of this document) and no additional data were submitted for allantoin or zinc acetate to support a "wound healing" use.

(Comment 9) One comment requested that compound benzoin tincture be included as a Category I topical skin protectant. The comment mentioned the conclusion of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (Cough-Cold Panel) that compound benzoin tincture was safe for use in boiling water as a steam inhalant for expectorant purposes (41 FR 38312 at 38360, September 9, 1976). The comment also cited the recommendation of the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products (Dental Panel) that compound benzoin tincture was safe and effective for use as an oral mucosal protectant (47 FR 22712 at 22746 and 22747, May 25, 1982). The comment cited acceptance of compound benzoin tincture in several pharmacopeias, experience over decades of use, and the low incidence of adverse reactions or significant side effects in the published literature. The comment cited several skin protectant uses from well-established references or current product labeling: "* * * to small cuts and to intact skin under occlusive plasters and bandages" (Ref. 5), "* * * ulcers, bedsores, cracked nipples, and fissures of the lips and anus" (Ref. 6), and "apply to the skin under adhesive dressings, to treat skin fissures and bedsores, to reduce skin sensitivity to adhesive plasters, and to prevent skin irritation in ischemic areas" (Ref. 7).

Compound benzoin tincture is included in the *USP* as a fixed formulation containing 10 percent benzoin, 2 percent aloe, 8 percent storax, 4 percent tolu balsam, and 74 to 80 percent ethanol (Ref. 8). The agency finds that use as a steam inhalant for expectorant purposes evaluated by the Cough-Cold Panel (41 FR 38312 at 38360) has little relevance to use as a skin protectant. Although the agency acknowledges that standard references (Refs. 5 and 6) and literature articles describe numerous uses for compound benzoin tincture, no data from controlled clinical studies were provided.

Gosselin et al. (Ref. 9) indicated that the alcohol in benzoin tincture would be responsible for major toxic effects if ingested. The Dental Panel discussed literature reports of three cases of irritation and hypersensitivity resulting from topical use of benzoin tincture (47 FR 22712 at 22746 and 22747). In addition, the published literature contains numerous other reports of allergic contact dermatitis and sensitivity attributed to compound benzoin tincture and benzoin tincture. Cullen, Tonkin, and May (Ref. 10) stated that the literature was replete with reports of cutaneous sensitivity to compound benzoin tincture and its components, citing reports following local application. Rademaker and Kirby (Ref. 11) reported two cases of bullous contact dermatitis to a skin adhesive spray and mentioned that Fisher (Ref. 12) recomm
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Based on these reports of adverse events and the availability of other monograph skin protectant ingredients, the agency concludes that compound benzoin tincture is not safe for use as a general OTC skin protectant ingredient and would be inappropriate for many of the uses included in this final monograph.

(Comment 10) One comment requested that camphorated metacresol be included as an active ingredient in the final monograph for OTC skin protectant drug products, as long as the amount of metacresol did not exceed 1.5 percent (by weight) and the amount of camphor did not exceed 3 percent. Noting that phenol (0.5 to 1.5 percent) and camphor (0.1 to 3 percent) were proposed Category I ingredients in the TFM for OTC external analgesic drug products (48 FR 5852 at 5867, February 8, 1983) and citing an agency letter (Ref. 20) agreeing that metacresol was less toxic than phenol, the comment contended that there should be no safety concern about products containing camphor and metacresol in these concentrations.

Because information has not been provided to demonstrate a skin protectant effect, camphorated metacresol is not included in this final monograph.

(Comment 11) One manufacturer submitted data and information (Refs. 21 and 22) to FDA's Miscellaneous External Panel in response to the call-for-data notice published in the **Federal Register** of November 16, 1973 (38 FR 31697). The data were for a drug product containing water-soluble chlorophyllins in an ointment and a solution dosage form with a label indication "to promote healing and to relieve itching and discomfort of minor wounds, burns, surface ulcers, cuts, abrasions and skin irritations."

The Miscellaneous External Panel was disbanded before reviewing these submissions. Subsequently, because the product label contained a claim for

wound healing and products with this claim had previously been included in the skin protectant rulemaking, the agency placed the submissions in the skin protectant rulemaking as a comment to the February 15, 1983, TFM, and the manufacturer submitted a more recent study on effectiveness for wound healing (Ref. 23).

The Dental Panel evaluated water-soluble chlorophyllins as oral wound healing agents in its report on OTC oral mucosal injury drug products (44 FR 63270, November 2, 1979) and concluded that water-soluble chlorophyllins were safe but that there were insufficient data available to permit final classification of effectiveness for OTC use as an oral wound healing agent (44 FR 63270 at 63286). The agency accepted the Dental Panel's classification in the TFM for OTC oral mucosal injury drug products (48 FR 33984 at 33991, July 26, 1983). No additional data were submitted and, in the final rule (51 FR 26112, July 18, 1986), the agency included water soluble chlorophyllins in the list of nonmonograph ingredients in 21 CFR 310.534.

The agency has reviewed the manufacturer's submissions (Refs. 21, 22, and 23). One submission (Ref. 21) contained information on various kinds of wounds that were treated with water-soluble chlorophyllins by health-care professionals. None were self-treatment conditions. Another (Ref. 22) contained translations of three foreign articles reporting laboratory and animal studies on water-soluble chlorophyllins that contain background information but do not support general recognition of safety and effectiveness in humans. A research report (Ref. 23) did not assess OTC uses, lacked subject and placebo controls, and questioned whether the observed effects were due to the products or the manner of caring for the wounds.

The agency concludes that the data submitted do not support effectiveness of water-soluble chlorophyllins for promoting wound healing for conditions treated with OTC skin protectant drug products.

(Comment 12) Cod liver oil was not categorized by the Panel for use as an OTC skin protectant because it was not included among the labeled ingredients in marketed products submitted to the Panel for review. In evaluating cod liver oil for use in diaper rash drug products, the agency considered the long history of clinical use as a skin protectant ingredient (55 FR 25204 at 25213, June 20, 1990).

In the rulemaking for OTC anorectal drug products, the Advisory Review Panel on OTC Hemorrhoidal Drug Products (Hemorrhoidal Panel) classified cod liver oil as Category I for use as an anorectal protectant and recommended a maximum daily dose of 10,000 I.U. (International Units equivalent to USP Units) for vitamin A and 400 I.U. for vitamin D (cholecalciferol) per 24 hours (45 FR 35576 at 35630, May 27, 1980). The Hemorrhoidal Panel stated that an extensive review of the literature on cod liver oil revealed no adverse effects when applied topically as a protectant and concluded that the effectiveness of cod liver oil, as a protectant, is due to its bland and soothing effect associated with its oily nature. In the TFM (53 FR 30756 at 30767, August 15, 1988) and final monograph (55 FR 31776 at 31780, August 3, 1990) for OTC anorectal drug products, the agency affirmed the Hemorrhoidal Panel's Category I classification and specified that cod liver oil may be used only in combination with one to three other protectant active ingredients.

The agency has surveyed the marketplace and determined that cod liver oil is marketed only in combination with other ingredients in several products with skin protectant claims (Refs. 3 and 24). One product contains 12.5 percent (Ref. 24), but in most cases the cod liver oil concentration is not provided.

Therefore, the agency is including cod liver oil as an active ingredient in skin protectant drug products in accord with § 347.20(a)(1) and (a)(2), only in combination with certain other skin protectant active ingredients, within the concentrations (5 to 13.56 percent) specified in § 347.10(e), provided that the product is labeled so that the amount of the product that is used in a 24-hour period represents a quantity that does not exceed 400 USP Units of vitamin D and 10,000 USP Units of vitamin A.

(Comment 13) In the notice of proposed rulemaking (54 FR 40808 at 40810), the agency stated that it was necessary to have publicly available chemical information for colloidal oatmeal. One manufacturer submitted a proposed standard for colloidal oatmeal, which it stated was patterned after standards for starch and psyllium (Ref. 25). The agency sent this information to the U.S. Pharmacopeial Convention (USPC) (Ref. 26). Compendial standards were proposed in the Pharmacopeial Forum of January and February 1992 (Ref. 27) and a final *USP* monograph became effective on November 15, 1992 (Ref. 28).

(Comment 14) One comment requested that colloidal oatmeal be included in the skin protectant monograph as a safe and effective ingredient for the claim: "For prompt temporary relief of itchy, sore, sensitive skin due to rashes, eczema/psoriasis, hemorrhoidal and genital irritations, diaper rash, chicken pox, prickly heat, hives, poison ivy/oak, and sunburn." The comment cited references (Refs. 29 through 33) to support this claim.

The agency previously discussed poison ivy/oak claims in comment 1 of the skin protectant poison ivy, oak, and sumac notice of proposed rulemaking (54 FR 40808 at 40809 to 40811). The agency has determined the additional references cited by the comment show that colloidal oatmeal can provide temporary skin protection and relieve minor irritation and itching due to a number of conditions. Further, the agency has no adverse reaction reports on file for colloidal oatmeal. Thus, the agency is expanding the indications for colloidal oatmeal in § 347.50(b)(4) in this final monograph. In addition, manufacturers can opt to select one or more of the "due to" conditions to list in the product's labeling. However, since no data were submitted using colloidal oatmeal for chicken pox, sunburn, or hives, these indications are nonmonograph. The agency will discuss a "prickly heat" claim in the skin protectant diaper rash drug products final rule.

(Comment 15) Two comments noted that the agency's proposed directions in § 347.50 (54 FR 40808 at 40818) for the use of colloidal oatmeal as a soak in a tub do not allow for the range of use concentrations or dosage forms that have been reported in the clinical literature and requested that FDA specify a use concentration range. The comment stated that colloidal oatmeal is unusual in comparison to other barrier skin protectants because it is often intended for dispersion in water and is formulated in a variety of other dosage forms.

One comment summarized and calculated the colloidal oatmeal concentrations used in baths (Refs. 32 and 34 through 41). The comment noted that the most common concentration ranges of colloidal oatmeal are from 0.007 to 10 percent in use but added that colloidal oatmeal is present in commercial products from 1 to 100 percent. Another comment recommended changing the proposed directions in § 347.50(d)(2) from one "cupful" to "up to a cupful."

The agency has reviewed the recommended concentrations of colloidal oatmeal reported in the literature and reference texts (Refs. 4, 29 through 32, 34 through 45, 47, 48, and 49) and has considered the range of

concentrations for colloidal oatmeal used in bath additive products and in other dosage forms. Products containing colloidal oatmeal have been formulated in the following dosage forms: Lotion (1 and 10 percent colloidal oatmeal), cleansing cream (8 percent colloidal oatmeal), shampoo (5 percent colloidal oatmeal), and cleansing bars (30, 50, and 51 percent colloidal oatmeal) (Refs. 4, 46, and 47). The agency has calculated the approximate minimum and maximum concentrations of colloidal oatmeal that have been used as follows: For regular colloidal oatmeal, a range of 0.023 to 0.625 percent when used as a tub bath soak (Refs. 29, 34 through 38, and 44), a range of 0.24 to 1.2 percent when used as a foot bath soak (Refs. 30, 31, and 34), a range of 0.24 to 15 percent in aqueous solution when used in a wet pack (Refs. 30, 31, 32, 34, and 45), and a range of 3.75 to 15 percent in aqueous solution when used as a topical lotion (Refs. 30, 32, and 34); for oilated colloidal oatmeal, a range of 0.003 to 0.03 percent when used as a tub bath soak (Refs. 35 and 39 through 43).

With regard to dosage forms, the agency agrees with the comment that colloidal oatmeal as a skin protectant does not need to be dosage-form specific and can be used in a variety of "barrier type" topical dosage forms, except for "cleanser type" topical dosage forms, for which the agency has no data to support use as a skin protectant. Therefore, based on the additional information that has been submitted, the agency is revising the directions for use in § 347.50(d)(2) in this final monograph.

(Comment 16) One comment requested that colloidal oatmeal be included in the skin protectant monograph for the claim: "For prompt temporary relief of itchy, sore, sensitive skin due to * * * hemorrhoidal and genital irritations * * *." The comment provided reports recommending use of colloidal oatmeal baths and creams for rectal itching and other conditions in the genital area (Refs. 50 through 54).

Claims for itching in the genital area (e.g., pruritus vulvae) are included in the rulemaking for OTC external analgesic drug products. A comment to that rulemaking (Ref. 55) specifically requested a claim for colloidal oatmeal for "prompt temporary relief of itchy, sore, sensitive skin due to rashes, eczema/psoriasis, hemorrhoidal and genital irritations, diaper rash, chicken pox, prickly heat, hives, poison ivy/oak, and sunburn." Therefore, the agency will address this comment in the final rule for OTC external analgesic drug products.

The agency concludes that the comment's requested claims for relief of rectal itching and hemorrhoids are similar to the indication (21 CFR 346.50(b)(1)) for OTC anorectal drug products that include protectant active ingredients under 21 CFR 346.14, and to the definition of a protectant drug under 21 CFR 346.3(i) as a drug that provides a physical barrier, forming a protective coating over skin or mucous membranes. Since colloidal oatmeal was not reviewed during any stage of the rulemaking for OTC anorectal drug products, interested parties should provide necessary information to demonstrate that colloidal oatmeal meets the standards of an OTC anorectal protectant active ingredient and petition the agency to include colloidal oatmeal in the final monograph for OTC anorectal drug products (Ref. 56).

(Comment 17) One comment requested that colloidal oatmeal be allowed to be combined with other Category I skin protectants for the treatment of minor irritation and itching caused by insect bites and poisonous plants. The comment cited reports using an oilated colloidal oatmeal bath additive to help treat various dermatoses.

The agency has reviewed the cited studies (Refs. 34, 43, 57, 58, and 59), and finds that these reports support the combination of colloidal oatmeal with mineral oil to treat the irritation, itching, and dryness of various dry skin dermatoses. The agency is including the combination of colloidal oatmeal and mineral oil in new § 347.20(a)(4) for the uses included in new § 347.50(b)(7) of this final monograph. Nevertheless, poison ivy, oak, and sumac are not exclusively dry skin dermatoses; they are characterized by a phase of weeping, oozing exudation. The studies cited by the comment fail to demonstrate the value of adding an additional skin protectant (an oilating component) for the treatment of these conditions in the exudative phase, and also fail to specify how many of the cases of contact dermatitis were due to poisonous plants. In addition, only one case of insect bite was identified in the studies. The agency concludes that the data are insufficient to support the combination of colloidal oatmeal with other skin protectants to treat insect bites and poison ivy, oak, and sumac.

(Comment 18) One comment responded to the agency's request in the skin protectant poison ivy, oak, and sumac notice of proposed rulemaking (54 FR 40808 at 40810) to provide information and directions to support the use of colloidal oatmeal on children under 2 years of age. The comment stated that most barrier type skin protectant active ingredients have not been restricted to any age group and submitted reports of use of colloidal oatmeal in infants (Refs. 34, 45, 50, 51, and 57). The comment added that the Miscellaneous External Panel had evaluated colloidal oatmeal and placed it in Category I for relief of itching claims with no age restrictions (Ref. 61).

The agency has reviewed the reports submitted by the comment, which described the effective use of colloidal oatmeal on infants and children from 2 months to 18 years of age for various dermatoses associated with dry skin. No adverse effects were reported. The Miscellaneous External Panel (Ref. 61) at its twenty-third meeting concluded that colloidal oatmeal, at all concentrations, is safe and effective for "the symptomatic relief and treatment of itching." Based on the Miscellaneous External Panel's evaluation and the references provided by the comment, the agency is including colloidal oatmeal in the final monograph for use on infants and children under 2 years of age in the same concentrations, dosage forms, and directions for use for adults.

(Comment 19) One comment noted that in the skin protectant poison ivy, oak, and sumac notice of proposed rulemaking the agency proposed (in § 347.50(c)(9)) a specific warning for colloidal oatmeal: "Take special care to avoid slipping when getting into and out of the tub" (54 FR 40808 at 40818). The comment agreed that a warning against slipping is proper and appropriate, but contended that the agency's warning is unnecessarily longer than the warning on its labels, "Take special care to avoid slipping." Furthermore, the comment contended, the reference to entering and leaving the tub may lessen the consumer's perception of need for care during bathing or when bathing a child.

The agency notes that a number of authors have expressed concerns about slipping in the bath tub with oil baths in general, and with colloidal oatmeal baths in particular (Refs. 29, 40, 44, 48, 54, and 62). Two authors (Refs. 29 and 48) recommended use of a mat to reduce the possibility of slipping. Accordingly, the agency has revised the warning, which appears in § 347.50(c)(5) of the final monograph, to read: "When using this product [bullet] to avoid slipping, use mat in tub or shower."

(Comment 20) One comment objected to the highly specific directions for colloidal oatmeal the agency proposed in § 347.50(d)(2) of the skin protectant poison ivy, oak, and sumac notice of proposed rulemaking (54 FR 40808 at 40818). The comment requested that

FDA modify the directions for use to allow for other concentrations and to address the use of other dosage forms, such as ointments, lotions, and cleansing bars. The comment objected to a specified frequency of use ("once or twice daily") because absorption of active agent seems unlikely to occur.

The agency has reviewed the literature and agrees with the comment that other directions may also provide safe and effective use concentrations. Since a bathtub, foot bath, sitz bath, or infant bath can be used to soak and a compress or wet dressing can be applied as a soak, the agency is including all of these forms of a "soak" in the final monograph. Colloidal oatmeal can also be formulated in other topical products intended for direct application (e.g., ointment, lotion), and the monograph provides directions for these products.

Frequent and prolonged exposure to water may have a drying effect. Authors have different views on recommended frequency and duration of bathing (Refs. 37, 48, and 63 through 67) depending on the condition. The Miscellaneous External Panel noted that bathing can dry the skin out and exacerbate some conditions (Ref. 68). Given the variety of conditions for which colloidal oatmeal preparations may be used, the agency agrees with the comment and is not specifying a frequency of use in the directions but is providing for a warning statement in § 347.50(c)(7) to fully inform consumers.

(Comment 21) One comment inquired whether two high-molecular weight dimethylpolysiloxanes, designated as SF96–350 and SF96–1000, were acceptable active ingredients for skin protectant use. The comment included general safety and toxicity information on silicone products, and stated that dimethicone, a proposed Category I skin protectant ingredient, belongs to the same chemical family as the dimethylpolysiloxanes.

In the notice of proposed rulemaking for OTC skin protectant diaper rash drug products, the agency stated that silicone is a general term, but it is often used to describe dimethicone (55 FR 25204 at 25218). The agency did not classify silicone per se because there are various silicone compounds and because the agency considered dimethicone, the only silicone ingredient for which data were submitted.

The agency notes that the information provided by the comment summarizes the results of chronic and acute toxicity studies and irritation studies for specific classes of silicones. However, no specific information was provided for the individual dimethylpolysiloxanes SF96–350 and SF96–1000. In addition, no information was provided to describe the chemical structure of these dimethylpolysiloxanes. The agency concludes that the data provided are inadequate to support general recognition of the safety and effectiveness of these ingredients for OTC skin protectant use in this final monograph.

(Comment 22) In the TFM for OTC skin protectant drug products, the agency discussed a submission on 2 percent glycerin and stated that the skin protectant final monograph would not be issued until these data were reviewed by the agency and interested persons provided an opportunity to comment on an agency proposal (48 FR 6820 at 6823). The submission (Ref. 69) contained data on the use of glycerin for the indications of dry skin, minor skin irritation, skin protectant, and chapping and included a double-blind study.

The agency has reviewed the data and determined that the study was inadequately controlled and failed to demonstrate that 2, 10, or 18 percent glycerin is effective for the indication "helps prevent and temporarily protects chafed, chapped, cracked, or windburned skin and lips," as proposed by the agency for 20 to 45 percent glycerin in the TFM for OTC skin protectant drug products (48 FR 6820 at 6832). The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Ref. 70). The agency concludes that glycerin at concentrations other than 20 to 45 percent is nonmonograph for use in OTC skin protectant drug products.

(Comment 23) One comment requested the agency to reopen the administrative record to include the ingredient "hard fat," as described in the "National Formulary" (NF) (Ref. 71), as a Category I skin protectant.

In the **Federal Register** of December 19, 1991 (56 FR 65873), the agency agreed with the petition that it would be appropriate to reopen the administrative record and include data and information on "hard fat" in the rulemaking for OTC skin protectant drug products. The agency stated that, based on its action in the rulemaking for OTC anorectal drug products (55 FR 31776), hard fat would be classified as a monograph ingredient in the final skin protectant monograph. Since no adverse comments on hard fat were received in response to this reopening of the administrative record, the agency is including hard fat in § 347.10 at concentrations of 50 to 100 percent as a single active ingredient. Hard fat is also allowed in permitted combinations in § 347.20(a)(1), (a)(2), (b), (c), and (d) of this final monograph. Products containing hard fat may be labeled for the indications in § 347.50(b)(1), (b)(2)(i), and (b)(2)(ii) and should bear the warnings in § 347.50(c)(1) through (c)(4) and the directions in § 347.50(d)(1). In a future issue of the **Federal Register**, the agency will address claims for hard fat in OTC skin protectant cold sore/fever blister drug products (*see* proposed § 347.50(b)(2)(ii), 55 FR 3362 at 3370).

(Comment 24) One comment requested that lanolin be categorized as an active ingredient in the skin protectant monograph for use as a single ingredient or in combination, as permitted by the monograph. In support of lanolin's safety and effectiveness as a skin emollient, the comment cited animal and human test data submitted to the Miscellaneous External Panel (Ref. 72), Kligman, Grove, and Studemayer (Ref. 73), and the Advisory Review Panel on OTC Ophthalmic Drug Products' (Ophthalmic Panel) Category I classification of lanolin as an ocular emollient for the treatment of conditions involving ocular membranes (43 FR 30002 at 30044 and 30045, May 6, 1980).

The agency has considered lanolin as a protectant or emollient active ingredient in several OTC drug rulemakings. In the TFM for OTC skin protectant diaper rash drug products (55 FR 25204 at 25218 to 25219), the agency determined that the data submitted supported the use of 15.5 percent lanolin as a skin protectant active ingredient only in combination with other skin protectant active ingredients for the treatment and prevention of diaper rash.

In the final rule for OTC ophthalmic drug products (53 FR 7076 at 7090, March 4, 1988), lanolin and anhydrous lanolin were included as monograph conditions at a 1 to 10 percent concentration in combination with one or more oleaginous emollients included in the monograph. In the final rule for OTC anorectal drug products (55 FR 31776 at 31780), lanolin was included as a monograph protectant active ingredient at concentrations of 50 percent and above as a single ingredient or between 12.5 and 50 percent in combinations.

The agency has surveyed the marketplace (Refs. 3, 74, 75, and 76), and found that lanolin is being marketed as a skin protectant both as a single ingredient and in combination with other ingredients. The concentration in two single ingredient products is 37 and 50 percent. In almost all cases, the concentration of the lanolin in the combination products is not provided. Based on the agency's market survey and its previous actions

in the rulemakings for OTC diaper rash, anorectal, and ophthalmic drug products, the agency is including lanolin in the final skin protectant drug products monograph as a single ingredient and in combination with certain other skin protectant active ingredients, depending on the labeled use of the product. The use concentration included in the final monograph is 12.5 to 50 percent in accord with the concentration of marketed single ingredient skin protectant drug products and the concentration used in anorectal protectant combination drug products. The use concentration of 15.5 percent proposed in § 347.10(o) for OTC diaper rash skin protectant drug products (55 FR 25204 at 25232) will be addressed in the final rule for those drug products.

(Comment 25) One comment submitted data (Refs. 77 through 89), including two clinical studies by Kaplan (Refs. 77, 78, 80, 81, and 84), in support of reclassifying LYCD from Category III to Category I as a wound healing aid. The first Kaplan study (Ref. 77) has been published (Ref. 90). The comment also submitted data included earlier in the rulemaking for OTC anorectal drug products and transcripts of meetings of the Hemorrhoidal Panel (Ref. 87).

The ingredient LYCD was reviewed by both the Hemorrhoidal Panel and the Topical Analgesic Panel. Neither panel found LYCD to be effective. The agency determined that the data were inadequate to support the use of LYCD in the final rule for OTC anorectal drug products (58 FR 46746, September 2, 1993).

The agency has reviewed the wound healing studies (Refs. 77, 78, 80, 81, and 84) submitted to this rulemaking for OTC skin protectant drug products and determined that the studies are inadequate to include LYCD as a wound healing aid in this final monograph. The agency's detailed comments and evaluations of the nonconfidential data are on file in the Dockets Management Branch (Refs. 91 and 92).

The agency also informed the company that additional information is needed on the chemical and physical characterization of LYCD before a final classification can be made and suggested the company provide information to establish a compendial monograph for the ingredient (Ref. 93). The company submitted information, both nonconfidential (Refs. 88 and 89) and confidential, but it also was not adequate. The agency's detailed comments on the information are on file in the Dockets Management Branch (Refs. 94 and 95).

(Comment 26) The agency has included in the rulemaking for OTC skin protectant drug products several submissions (Refs. 96, 97, and 98) for drug products containing mineral oil that were originally submitted to the Miscellaneous External Panel for review. One submission (Ref. 96) did not contain any data on mineral oil as an individual ingredient and the other submissions (Refs. 97 and 98) were discussed in the TFM for OTC skin protectant diaper rash drug products (55 FR 25204 at 25220 to 25221). The agency concluded that the ingredient's physical properties were sufficient, along with the Category I findings of two other panels (Hemorrhoidal and Ophthalmic Panels), to support the effectiveness of mineral oil in § 347.10(p) of the skin protectant diaper rash TFM (55 FR 25204 at 25232) for diaper rash claims proposed in § 347.50(b)(5). In this final monograph for OTC skin protectant drug products, mineral oil in the first concentration listed in § 347.10(l) (50 to 100 percent) may be labeled for the claims listed in § 347.50(b)(1) and (b)(2). In addition, mineral oil in the second concentration listed in § 347.10(1) (30 to 35 percent) when combined with colloidal oatmeal may be labeled for the claims listed in § 347.50(b)(7).

(Comment 27) One comment urged FDA to consider a single statement of identity for the ingredient petrolatum because of its multi-purpose uses in OTC drug products. The comment suggested the term "protectant."

Petrolatum is generally recognized as safe and effective in two other OTC drug final monographs: Ophthalmic (part 349 (21 CFR part 349)) and anorectal (21 CFR part 346). The statement of identity for ophthalmic use is "lubricant" or "emollient (lubricant) eye ointment" (*see* § 349.65(a)).

The agency previously considered a related issue in the proposed rulemaking for OTC anorectal drug products (*see* comment 39, 53 FR 30756 at 30771) and determined that a comment's suggested statement of identity (topical protectant and lubricant) did not make it clear that such a product could be used anorectally and thus did not fully satisfy the requirements of § 201.61(b). The agency believes that the same is true of the currently suggested statement of identity "protectant." Thus, the agency is not adopting a single statement of identity for the ingredient petrolatum and is using "skin protectant" as the statement of identity for drug products containing petrolatum included in this final monograph (part 347).

(Comment 28) One comment argued that petrolatum should be exempt from the "directions for use" proposed in § 347.50(d), citing petrolatum's long history of consumer use, efficacy, and safety and contending that petrolatum meets the requirements for such exemption under § 201.116 (21 CFR 201.116).

The agency disagrees. Section 201.116 allows for exemption from section 502(f)(1) of the act which requires adequate directions for use, if adequate directions for common uses are known to the ordinary individual. While some individuals may know that petrolatum may be applied as needed, the agency believes that not all people who use this drug would know that it can be applied on an as needed basis. Therefore, the agency is requiring the standard direction in § 347.50(d)(1) for products that contain petrolatum.

(Comment 29) One comment contended that petrolatum should be exempt from the warnings proposed in the TFM (48 FR 6820 at 6832 to 6833). The comment argued that sufficient evidence to exempt these warnings is provided by the universal use of petrolatum over many decades for a wide variety of topical indications, the clinical and marketing experience over this long period of extensive and universal use, the Panel conclusion that "large amounts of petrolatum are essentially nontoxic when ingested * * *" (43 FR 34628 at 34639), the results of a long-term chronic feeding study by Oser et al. (Ref. 99) as demonstrating safety on ingestion, and the fact that petrolatum is regulated as an approved direct food additive (under § 172.880 (21 CFR 172.880)) and is listed in the Food Chemicals Codex (Ref. 100).

Although the comment suggested a revision, it agreed in principle with the warning "Not to be applied over deep or puncture wounds, infections, or lacerations. Consult a doctor." A second comment requested, in the interest of brevity, clarity, and conservation of scarce label space, that the warning be shortened to read: "Do not apply over deep or puncture wounds or infections."

The agency discussed the importance of each of the proposed warnings in comments 25 through 31 of the TFM (48 FR 6820 at 6828 to 6830) and stated that these warnings are necessary for petrolatum used as a skin protectant. In comment 31 of the TFM, however, the agency proposed not to require the "For external use only warning" for all products (including those containing petrolatum) formulated as lip balms. The agency is finalizing that proposal in this document.

In this final monograph, products containing the skin protectant ingredients mineral oil or sodium bicarbonate may omit the "For external use only" warning if they also provide labeling for oral use of the product. The agency believes that it could be confusing to consumers if products that contain petrolatum do not have the "For external use only" warning. Therefore, the agency is not exempting petrolatum (except in lip protectant products) from the "For external use only" warning in §§ 201.66(c)(5)(i) and 347.50(c)(1).

The agency considers the warning about not getting the product into the eye useful to help prevent possible improper use of skin protectant drug products which are often marketed in nonsterile, multiple use containers. The agency believes that the first comment misconstrued the purpose of the "if condition worsens" warning (§ 347.50(c)(3) of this final monograph). The warning is intended to direct consumers to seek medical attention for a condition if it gets worse or has not improved after 7 days of treatment and not to set 7 days as a maximum safe treatment period. The agency has shortened this warning for products containing petrolatum (or white petrolatum) as a single ingredient to state: "See a doctor if condition lasts more than 7 days."

With regard to the suggestion that the warning in § 347.50(c)(4) be revised, after the submission of this comment, the agency published a similar warning for OTC first aid antibiotic drug products (52 FR 47312 at 47324, December 11, 1987) and OTC first aid antiseptic drug products (56 FR 33644 at 33677, July 22, 1991). The agency is revising the warning in § 347.50(c)(4), accordingly, in the new format required by § 201.66.

(Comment 30) One comment considered the two general warnings in § 330.1(g) unnecessary for 100 percent petrolatum. The comment cited two references (Refs. 99 and 100) to support its contention that petrolatum is a uniquely safe OTC drug and presents no risk to the health of children from misuse, overuse, or abuse.

The agency finds the information in the cited references (as well as the information in § 172.880 regarding the regulation of petrolatum as an approved food additive) insufficient to support an exemption for 30 to 100 percent petrolatum from the two general warnings in § 330.1(g). References 99 and 100 list petrolatum concentrations at 0.02 to 5 percent, significantly lower than the concentration range included in the monograph. The agency revised the wording of these warnings in § 330.1(g) in the final rule for the new OTC drug product labeling format (64 FR 13254 at 13294).

(Comment 31). One comment stated that the agency's proposed directions for sodium bicarbonate for use as a soak in a tub allow for a topical use concentration of about 0.3 percent, which is less than the dosage range for topical use of 1 to 100 percent (54 FR 40808 at 40818).

The agency has reviewed its calculations and agrees with the comment that the proposed directions for use as a soak in a tub allow for a topical concentration of less than 1 percent, depending on the amount of water in the tub and the size of the cup used. However, these directions are consistent with those suggested in the literature (Refs. 101 through 104). When these measurements are made by consumers, they may not be precise. Accordingly, in this final monograph, the agency recognizes that it is not possible or critical to make a precise determination of the use concentration for this ingredient. Thus, the agency has revised its recommendations.

(Comment 32) The agency has considered topical starch (formerly known as corn starch) in several rulemakings. In the advance notice of proposed rulemaking for OTC skin protectant drug products (43 FR 34628 at 34636), the TFM for OTC skin protectant drug products (48 FR 6820 at 6828), the TFM for OTC skin protectant poison ivy, poison oak, poison sumac, and insect bites drug products (54 FR 40808 at 40811 to 40812), the Miscellaneous External Panel's statement on OTC diaper rash drug products (47 FR 39436 at 39439, September 7, 1982), the TFM for OTC skin protectant diaper rash drug products (55 FR 25204 at 25232), and the TFM (53 FR 30756 at 30782) and final monograph (55 FR 31776 at 31780) for OTC anorectal drug products.

Based on the evaluations of the Topical Analgesic, Miscellaneous External, and Hemorrhoidal Panels, and the subsequent inclusion of topical starch as a protectant in the final monograph for OTC anorectal drug products and in the TFM for OTC diaper rash drug products, the agency is including topical starch at a concentration of 10 to 98 percent as an active ingredient under § 347.10(q) of this final monograph for OTC skin protectant drug products. The agency is including a minor skin irritation indication for the skin protectant uses of topical starch in § 347.50(b)(6). Because topical starch should not be used on broken skin, other conditions (e.g., cuts, scrapes, chapped/cracked skin and lips) are not included in this final monograph. Warnings applicable to topical starch drug products in a powder dosage form are included in § 347.50(c)(6).

(Comment 33) Two comments from the same company requested that vitamins A and D be added to the list of Category I active ingredients in the skin protectant monograph. The comments stated that shark liver oil, which contains significant quantities of vitamins A and D, is an oleaginous substance that provides lubricity and emolliency. The comments mentioned that vitamins A and D, like cod and shark liver oils, have an emollient nature that provides a physical barrier to an irritant and aids in the temporary relief of minor skin irritations. The comments added that these oleaginous substances can lessen dermal injury caused by friction and lessen itching and dryness caused by water loss from the stratum corneum, thereby providing additional protection for exposed skin. The comments cited the Hemorrhoidal Panel's recommendations on the safety and topical use of vitamins A and D (45 FR 35576 at 35630 and 35634). Another comment stated that a number of the claims recommended by the Hemorrhoidal Panel in the advance notice of proposed rulemaking for OTC skin protectant drug products (43 FR 34628 at 34648) should be listed in the monograph for the ingredients vitamin A and vitamin D.

The Hemorrhoidal Panel did not review vitamin A or vitamin D (cholecalciferol) as single ingredients for use as protectants in OTC anorectal drug products but did consider these ingredients in its review of ingredients used for wound healing (45 FR 35576 at 35655 and 35656). The Hemorrhoidal Panel concluded that the data submitted were insufficient to prove effectiveness of vitamins A and D as wound healing agents and classified these ingredients in Category III for this use (45 FR 35576 at 35655 and 35656). The agency did not include vitamins A or D in the anorectal final monograph because no data were submitted to support the effectiveness of these ingredients for protectant uses. However, the Hemorrhoidal Panel recommended that cod liver and shark liver oils be included in the Category I list of active ingredients for use as protectants in OTC anorectal drug products (45 FR 35576 at 35630 and 35634) and the agency concluded that these oils are monograph ingredients (55 FR 31776 at 31780). The agency pointed out in its proposed rulemaking for OTC diaper rash drug products (55 FR 25204 at 25225) that vitamins A and D have not been classified as skin protectants in

any rulemaking in the OTC drug review, concluded that additional data are needed, and placed these ingredients in Category III.

Because no data were submitted to support the effectiveness of vitamins A and D for skin protectant uses, the agency concludes that these ingredients are nonmonograph when used individually or in combination other than as a component of cod liver oil listed in § 347.10(e) of this final monograph.

(Comment 34) In the TFM for OTC first aid antiseptic drug products (56 FR 33644 at 33650), the agency deferred data on a physical barrier cream product with protective claims to the rulemaking for OTC skin protectant drug products. The cream product contains a combination of ingredients: Cetyl alcohol, glyceryl stearate, isopropyl palmitate, stearyl alcohol, and beeswax, labeled as "skin wound protectant" ingredients. The product labeling states "helps protect minor cuts, burns, and skin irritations against contamination." This claim is very similar to the claim included in § 347.50(b)(1) of this final monograph. The submission included the results of animal and human safety studies on the finished product, including LD50 in mice and rats, acute dermal toxicity studies in rabbits, 48-hour and 72-hour primary irritation studies in humans using occlusive patch tests, and 21-day cumulative irritation studies. The submission also included reports of studies on the cream product's protective barrier effect and a clinical study to evaluate safety and effectiveness. The clinical study was described as a randomized, controlled, double-blind, parallel-group comparison of two products to determine the cream product's safety and effectiveness under actual use conditions. The control formulation was not provided.

The agency finds the submitted data insufficient to establish the skin protectant effect of any of the ingredients present in the cream product because the contribution, if any, of each of the individual active ingredients cannot be determined. The Panel recommended that there need be no limit to the number of skin protectant ingredients that may be combined in a product (43 FR 34628 at 34631). However, each ingredient must make a contribution to the claimed effect(s) in order to be deemed an active ingredient (§ 330.10(a)(4)(iv)). Further, the agency notes that the Miscellaneous External Panel classified the ingredients cetyl alcohol and stearyl alcohol as inactive in the advance notice of proposed rulemaking for OTC alcohol drug products (47 FR 22324 at 22326, May 21, 1982). In addition, the Dental Panel classified beeswax as inactive in the advance notice of proposed rulemaking for OTC drug products for the relief of oral discomfort (47 FR 22712 at 22715). No additional data on these three ingredients have been submitted to any rulemaking in the OTC drug review. The other two listed active ingredients, glyceryl stearate and isopropyl palmitate, have not been considered in any rulemaking in the OTC drug review. Consequently, the agency concludes that the safety and effectiveness data are insufficient on beeswax, cetyl alcohol, glyceryl stearate, isopropyl palmitate, and stearyl alcohol. Therefore, these ingredients are being included in § 310.545(a)(18) as nonmonograph.

(Comment 35) Two comments contended that, as a class, skin protectant ingredients may be combined with more different types of therapeutic categories than any other class of ingredients. However, in the TFM, proposed § 347.20 does not list any ingredients other than skin protectant ingredients that may be combined. The comments stated that skin protectant ingredients have been found appropriate for use in combination with several other ingredient categories in other OTC drug product rulemakings. The comments requested that the agency include a provision in the final monograph allowing the combination of skin protectant ingredients with any therapeutic class of ingredients when such a combination has been found appropriate by any other OTC advisory review panel.

Proposed § 347.20 in the skin protectant TFM was published in the **Federal Register** on February 15, 1983, before the TFMs for many other categories of OTC drug products. Subsequently, based on panel recommendations in other OTC drug rulemakings and the TFMs for OTC external analgesic drug products (48 FR 5852 at 5868), OTC first aid antiseptic drug products (56 FR 33644 at 33677), and OTC sunscreen drug products (58 FR 28194 at 28296, May 12, 1993), this final monograph includes skin protectant active ingredients in combination with other ingredients from these therapeutic classes.

Therefore, the agency has further considered and expanded the ingredient combinations included in § 347.20 of this final monograph, including skin protectant-sunscreen combinations in § 347.20(d). The agency is also amending the final monograph for OTC sunscreen drug products (64 FR 27666, May 21, 1999) to include sunscreen-skin protectant drug products. Further, the agency may be expanding the permitted combinations in § 347.20(b) and (c) as data submitted to the rulemakings for OTC external analgesic and first aid antiseptic drug products are evaluated and the final monographs for those OTC drug classes are issued.

III. Conclusion

Based on the available evidence, the agency is issuing a final monograph establishing conditions under which OTC skin protectant drug products are generally recognized as safe and effective and not misbranded. Any drug product labeled, represented, or promoted for use as an OTC skin protectant drug that contains any of the ingredients listed in § 310.545(a)(18)(i)(A) or (a)(18)(i)(B) or that is not in conformance with the monograph (part 347) may be considered a new drug within the meaning of section 201(p) of the act (21 U.S.C. 321(p)) and misbranded under section 502 of the act. Such a drug product cannot be marketed for skin protectant uses unless it is the subject of an approved application under section 505 of the act (21 U.S.C. 355) and part 314 of the regulations (21 CFR part 314). An appropriate citizen petition to amend the monograph may also be submitted in accord with 21 CFR 10.30 and 330.10(a)(12)(i). Any OTC skin protectant drug product initially introduced or initially delivered for introduction into interstate commerce after the compliance dates of the final rule for § 310.545(a)(18)(i)(A) or this final rule that is not in compliance with the regulations is subject to regulatory action.

Our decision to revise the warnings set forth in this final rule is based on comments made in response to the proposed rule. Mandating warnings in an OTC drug monograph does not require a finding that any or all of the OTC drug products covered by the monograph actually caused an adverse event, and FDA does not so find. Nor does FDA's requirement of warnings repudiate the prior OTC drug monographs and monograph rulemakings under which the affected drug products have been lawfully marketed. Rather, as a consumer protection agency, FDA has determined that warnings are necessary to ensure that these OTC drug products continue to be safe and effective for their labeled indications under ordinary conditions of use as those terms are defined in the the act. This judgment balances the benefits of these drug products against their potential risks (*see* 21 CFR 330.10(a)).

FDA's decision to act in this instance need not meet the standard of proof required to prevail in a private tort action (*Glastetter* v. *Novartis Pharmaceuticals, Corp.*, 252 F. 3d 986, 991 (8th Cir. 2001)). To mandate warnings, or take similar regulatory action, FDA need not show, nor do we allege, actual causation. For an expanded discussion of case law supporting FDA's authority to require such warnings, *see* the final rule entitled "Labeling of Diphenhydramine-Containing Drug Products for Over-the-Counter Human Use" (67 FR 72555, December 6, 2002).

IV. Labeling Guidance

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA established a standardized format and standardized content for the labeling of OTC drug products. Table 1 of this document shows how the warnings proposed in the TFM have been revised in this final rule based on comments received and using the new format in § 201.66. Using the format in § 201.66(c)(4), the warnings in §§ 347.50(c) and 347.52(c) appear as follows:

TABLE 1.—REVISION OF PROPOSED MONOGRAPH WARNINGS TO NEW FORMAT

Skin Protectant Tentative Final Monograph	Skin Protectant Final Monograph
Not to be applied over deep or puncture wounds, infections, or lacerations. Consult a doctor. Do not use on broken skin.	Do not use on • deep puncture wounds • animal bites • serious burns • broken skin[1]
Avoid contact with the eyes. Keep powder away from child's face to avoid inhalation, which can cause breathing problems. Take special care to avoid slipping when getting into and out of the tub.	When using this product • do not get into eyes • keep away from face and mouth to avoid breathing it • in some skin conditions, soaking too long may overdry • to avoid slipping, use mat in tub or shower
If condition worsens or does not improve within 7 days, consult a doctor.	Stop use and ask doctor if • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days
For external use only.	For external use only[2]

[1] Only required for powder products containing kaolin or topical starch. *See* § 347.50(c)(6).
[2] In bold type on the line immediately following the line for the Warnings heading. *See* § 201.66(c)(5)(i) and (d)(6).

Section 201.66(d)(10) (21 CFR 201.66(d)(10)), which sets forth format and content requirements for OTC drug product labeling, establishes a modified labeling format for small packages that need more than 60 percent of their total surface area available to bear labeling to meet the format requirements of § 201.66(d)(1) through (d)(9). The agency stated in the final rule that established these labeling requirements that it would consider additional approaches for accommodating certain products in their respective monographs, taking into consideration the risks and benefits of the drug, the intended use, and the need to communicate limitations or restrictions about the use of the product to the target population (64 FR 13254 at 13270).

In the final monograph for OTC sunscreen drug products (64 FR 27666 at 27678), the agency discussed modified warnings for lip balm products and stated that it expects to adopt the same modifications when it issues the final monograph for OTC skin protectant drug products. Accordingly, the agency is establishing additional labeling exemptions for lip balm/lip protectant products that meet the criteria established in § 201.66(d)(10). The specifications for products formulated and labeled as a lip protectant or lip balm that meet the criteria established in § 201.66(d)(10) are in § 347.50(e) of the skin protectant final monograph. In making this determination for lip protectant/lip balm products, the agency considered a number of factors that were discussed in the final rule that established the new OTC drug product labeling format in § 201.66 (64 FR 13254 at 13270). These factors include the risks and benefits of the drug, the intended use, and the need to communicate limitations or restrictions about the use of the product to the target population. Lip protectant/lip balm products are typically packaged in small amounts, applied to limited areas of the body, have a high therapeutic index, carry extremely low risk in actual consumer use situations, provide a favorable public health benefit, require no specified dosage limitation, and require few specific warnings and no general warnings (e.g., pregnancy or overdose warnings). For these reasons, the agency has concluded that minimal information is needed for the safe and effective use of such products.

The agency is also including in this final rule some modified labeling requirements in § 347.50(f) of the final monograph for products containing only cocoa butter, petrolatum, or white petrolatum singly or in combination with each other when marketed other than as a lip protectant or lip balm. In making this decision for cocoa butter, the agency considered the factors discussed in the previous paragraphs and the Panel's recommendations on cocoa butter. The Panel stated in its safety evaluation of cocoa butter (43 FR 34628 at 34635) that "No reports regarding the safety of cocoa butter have been specifically identified. However, the Panel recognizes that its safety has been established by its wide and continuous use in pharmaceutical products and cosmetics. Clinical and marketing experience has confirmed that cocoa butter is safe in the dosage range used as a skin protectant." Thus, these products have an extremely low risk in actual consumer use situations. In addition, the agency has considered the OTC uses for this ingredient as providing temporary protection of minor cuts, scrapes, burns, and chapped or cracked skin and lips. Application to these areas for these uses will likely be infrequent and to limited areas of the body. In making this decision for petrolatum and white petrolatum, the agency considered the factors discussed in the previous paragraphs, the Panel's recommendations, and the evidence and data described in section II., comment

29 of this document. The Panel stated in its safety evaluation of petrolatum preparations (43 FR 34628 at 34639) that "Petrolatum is not absorbed through intact or injured skin and is neither sensitizing nor irritating. Large amounts are essentially nontoxic when ingested in liquid laxative preparations. Clinical and marketing experience has confirmed that petrolatum is safe in the OTC dosage range used as a skin protectant." As noted for cocoa butter, the agency has considered the OTC uses for these ingredients and believes that application to these areas for these uses will likely be infrequent and to limited areas of the body. The agency concludes that petrolatum and white petrolatum have an extremely low risk in actual consumer use situations. Moreover, both products provide a favorable public health benefit, require no specified dosage limitation, and require few specific warnings nad no general warnings (e.g., pregnancy or overdose warnings).

V. Stay of § 347.20(d) and Part 352

The agency is lifting the stay for the sunscreen monograph in part 352 for the sole purpose of amending the codified language as set forth in the skin protectant final monograph. Once the codified language is amended, part 352 will remain stayed indefinitely. The agency is also staying § 347.20(d) because it involves combination products that contain sunscreen active ingredients. To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(3)(A). Alternatively, the agency's implementation of this action without opportunity for public comment comes within the good cause exceptions in 5 U.S.C. 553(b)(3)(B) in that obtaining public comment is impracticable, unnecessary, and contrary to the public interest. The agency complied with the notice and comment procedures in 5 U.S.C. 553 when it issued the skin protectant final monograph set forth in this notice. The agency is lifting the stay for part 352 in order to revise part 352 to be consistent with that monograph. As the agency stated in the **Federal Register** of December 31, 2001 (66 FR 67485), FDA intends to publish a proposal to amend part 352 in order to develop a comprehensive sunscreen monograph that addresses formulation, labeling, and testing requirements for both ultraviolet B (UVB) and ultraviolet A (UVA) radiation protection. That amendment will propose a new effective date for part 352 and for § 347.20(d). Thus, there will be an opportunity for public comment on the new effective date within the proposed amendment to part 352. In accordance with 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether this partial stay should be modified or revoked.

VI. Analysis of Impacts

An analysis of the costs and benefits of this regulation, conducted under Executive Order 12291, was discussed in the TFM for OTC skin protectant drug products (48 FR 6820 at 6831). The agency certified that under the Regulatory Flexibility Act the proposed rule would not have a significant economic impact on a substantial number of small entities. No comments were received on the economic impact of this rulemaking.

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule may have a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement and economic analysis before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). The proposed rules that have led to the development of this final rule were published on February 15, 1983, and October 3, 1989, before the Unfunded Mandates Reform Act of 1995 was enacted. The agency explains in this final rule that the final rule will not result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year.

The agency concludes that this final rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. The final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation adjusted statutory threshold is about $110 million.

The purpose of this final rule is to establish allowable monograph ingredients and labeling under which OTC skin protectant drug products are generally recognized as safe and effective. Of the 29 active ingredients considered in this final rule, 19 are being included in the final monograph while 10 are not. Of the 10 not included, 1 is deferred to the final rule on OTC skin protectant diaper rash drug products and 1 may be included pending development of a USP/NF monograph for the ingredient.

Products containing the remaining eight active ingredients will need to be reformulated to delete and replace the ingredient(s) with another (monograph) skin protectant active ingredient or an inactive vehicle. As discussed in section II, comment 34 of this document, at least three and maybe five of these eight ingredients also could be used as inactive (vehicle) ingredients in topical drug products. Therefore, some of these manufacturers may be able to relabel their products without reformulations to comply with this rule.

The agency's Drug Listing System identifies approximately 4,000 drug products containing these 8 ingredients; however, only a limited number of these products list these ingredients as active for a skin protectant drug product (table 2) in the next paragraph of this document.

TABLE 2.—NUMBER OF MARKETERS AND PRODUCTS LISTING INGREDIENTS AS ACTIVE

Ingredient	No. of Marketers	No. of Products
Beeswax	2	2
Boric acid	21	22
Cetyl alcohol	3	9

The cost to reformulate a product will vary greatly depending on the nature of the change in formulation, the product, the process, and the size of the firm. Some of the 33 manufacturers of the 50 products containing nonmonograph active ingredients may not have to reformulate. For those products that need reformulation, the cost can be significant. Because of the large number of monograph active ingredients available for reformulation, no manufacturer should need to change its

dosage form; however, it will have to redo the validation (product, process, new supplier), conduct stability tests, and change master production records. The agency estimates the cost of reformulation to range from $100,000 to $500,000. Therefore, if all 50 products are reformulated, the midpoint of the cost estimate implies total costs of $15 million. However, the agency believes the total costs will be much smaller because not all manufacturers will have to reformulate and some may choose to discontinue a product line if sales are too low to justify the added cost and/or they also produce substitute products that do not require reformulation.

Because these products must be manufactured in compliance with the pharmaceutical current good manufacturing practices (21 CFR parts 210 and 211), all firms would have the necessary skills and personnel to perform these tasks either in-house or by contractual arrangement. No additional professional skills are needed.

This final rule establishes the monograph for OTC skin protectant drug products and will require relabeling of all products covered by the monograph. The agency's Drug Listing System identifies approximately 1,300 OTC skin protectant drug products containing the 29 ingredients covered by this final rule. It is likely that there are a number of additional products that are not currently included in the agency's system. Also, as indicated previously, a number of the skin protectant ingredients can be and often are used as inactive ingredients in many of the OTC drug products included in the Drug Listing System. While it is difficult to determine an exact number, the agency estimates that 2,000 to 2,500 OTC stockkeeping units (SKUs) (individual products, packages, and sizes) will need to be relabeled based on this final rule. Based on information in the Drug Listing System, the agency estimates there are at least 200 manufacturers and 700 marketers of these products. Marketers, however, generally do not incur these costs because manufacturers of OTC drug products are usually responsible for product labeling, testing, and formulation.

Estimates of relabeling costs for the type of changes required by this rule vary greatly and range from $500 to $15,000 per SKU depending on whether the products are nationally branded or private label. The agency assumes the same weighted average cost to relabel (i.e., $3,600 per SKU) that it estimated for the final rule requiring uniform label formats of OTC drug products (64 FR 13254 at 13279 to 13281). Assuming 2,000 to 2,500 affected OTC SKUs in the marketplace, total one-time costs of relabeling would be $7.2 to $9.0 million. Because frequent labeling redesigns are a recognized cost of doing business in the OTC drug industry, these costs may be less. Manufacturers that make voluntary market-driven changes to their labeling during the implementation period can implement the regulatory requirements for a nominal cost. The final rule would not require any new reporting or recordkeeping activities.

This final rule may have an economic impact on some small entities. The agency's Drug Listing System indicates that about 700 marketers will need to relabel, and that this relabeling will be prepared by about 200 manufacturers, most of which are private label or contract manufacturers. Based on the Small Business Administration's determination that a small firm in this industry has fewer than 750 employees, roughly 70 percent of the firms are considered small. The economic impact on any particular firm is very difficult to measure, because it will vary with the type and number of products affected, the number of SKUs per product, and the ability to coordinate these label changes with those required for other purposes. For example, assuming average industry costs, a small company that had 5 products with 3 SKUs each, for a total of 15 SKUs, would experience a one-time cost of $54,000 (15 x $3,600). A small private label manufacturer with the same product line and 10 customers per SKU, for a total of 150 SKU's, would experience a one-time cost of $540,000 (150 x $3,600). If one or more products needed to be reformulated, the costs would increase by $100,000 to $500,000 per reformulation. Some of these relabeling costs may be mitigated to the extent that manufacturers can coordinate this relabeling with relabeling requirements for the standardized format and content labeling requirements of OTC drug products (§ 201.66) and the sunscreen rule. Products with annual sales less than $25,000 have 1 additional year. Therefore, many of the labeling revisions may be done in the normal course of business. These steps should help to minimize the impact on small entities by providing enough time for implementation to enable entities to use up existing labeling stock. The agency believes that these actions provide substantial flexibility and reductions in cost for small entities.

The agency considered but rejected several labeling alternatives: (1) A shorter or longer implementation period, and (2) an exemption from coverage for small entities. While the agency believes that consumers would benefit from having this new labeling in place as soon as possible, a longer time period would unnecessarily delay the benefit of new labeling and revised formulations, where applicable, to consumers. The agency rejected an exemption for small entities because the new labeling and revised formulations, where applicable, are also needed by consumers who purchase products marketed by those entities. However, a longer (24-month) compliance date is being provided for products with annual sales less than $25,000.

This analysis shows that the agency has undertaken important steps to reduce the burden to small entities. Thus, this economic analysis, together with other relevant sections of this document, serves as the agency's final regulatory flexibility analysis, as required under the Regulatory Flexibility Act.

VII. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. Environmental Impact

The agency has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment

nor an environmental impact statement is required.

X. Request for Comments

This final rule includes reduced labeling requirements for products formulated and labeled as a lip protectant that meet the criteria established in § 201.66(d)(10) (*see* § 347.60(e)); for products containing only cocoa butter, petrolatum, or white petrolatum identified in § 347.10(d), (m), and (r), used singly or in combination with each other, and marketed other than as a lip protectant (*see* § 347.60(f)); for sunscreen drug products labeled for use only on specific small areas of the face (e.g., lips, nose, ears, and/or around eyes) and that meet the criteria established in § 201.66(d)(10) (*see* § 352.52(f)); and for combinations of skin protectant and sunscreen active ingredients (*see* § 352.60(b)(2), (c), and (d)). Some of this reduced labeling results from the modified labeling format for OTC drug products in § 201.66(d)(10), which did not exist when the TFM and amended TFM were published. Some of this reduced labeling is in response to comments specifically addressing petrolatum and white petrolatum, which the agency has extended to cocoa butter. The agency is providing 90 days for comment on the specific labeling requirements discussed in this section. Comments should be identified with the docket number found in brackets in the heading of this document. Three copies of all mailed comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Received comments may be seen in the Dockets Management Branch (*see* **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday. If the comments justify a change in labeling, the agency will propose to amend the final monographs accordingly at a later date. Because the amendment process can take a significant period of time, manufacturers of the products covered by this final rule should implement the labeling stated therein at this time, unless the compliance date has been stayed.

XI. References

The following references are on display in the Dockets Management Branch (*see* **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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21. OTC Vol. 160034.

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List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Parts 347 and 352

Labeling, Over-the-counter drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 310, 347, and 352 are amended as follows:

PART 310—NEW DRUGS

■ 1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

■ 2. Section 310.545 is amended by revising paragraphs (a)(18)(i), (a)(18)(v), (a)(18)(vi), and (d)(1), and by adding paragraph (d)(32) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(18) * * *

(i)(A) *Ingredients—Approved as of May 7, 1991.*

Allantoin (wound healing claims only)
Sulfur
Tannic acid
Zinc acetate (wound healing claims only)

(B) *Ingredients—Approved as of* June 4, 2004; June 6, 2005, *for products with annual sales less than $25,000.*

Beeswax
Bismuth subnitrate
Boric acid
Cetyl alcohol
Glyceryl stearate
Isopropyl palmitate
Live yeast cell derivative
Shark liver oil
Stearyl alcohol

* * * * *

(v) *Insect bite and sting drug products.*

(A) *Ingredients—Approved as of May 7, 1991.*

Alcohol
Alcohol, ethoxylated alkyl
Ammonia solution, strong
Ammonium hydroxide
Benzalkonium chloride
Camphor
Ergot fluid extract
Ferric chloride
Menthol
Peppermint oil
Phenol
Pyrilamine maleate
Sodium borate
Trolamine
Turpentine oil
Zirconium oxide

(B) *Ingredients—Approved as of* June 4, 2004; June 6, 2005, *for products with annual sales less than $25,000.*

Beeswax
Bismuth subnitrate
Boric acid
Cetyl alcohol
Glyceryl stearate
Isopropyl palmitate
Live yeast cell derivative
Shark liver oil
Stearyl alcohol

(vi) *Poison ivy, poison oak, and poison sumac drug products.*

(A) *Ingredients—Approved as of May 7, 1991.*

Alcohol
Anion and cation exchange resins buffered
Benzethonium chloride
Benzocaine
Benzyl alcohol
Bismuth subnitrate
Bithionol
Boric acid
Camphor
Cetalkonium chloride
Chloral hydrate
Chlorpheniramine maleate
Creosote
Diperodon hydrochloride
Diphenhydramine hydrochloride
Eucalyptus oil
Ferric chloride
Glycerin
Hectorite
Hydrogen peroxide
Impatiens biflora tincture
Iron oxide
Isopropyl alcohol
Lanolin
Lead acetate
Lidocaine
Menthol
Merbromin
Mercuric chloride
Panthenol
Parethoxycaine hydrochloride
Phenol
Phenyltoloxamine dihydrogen citrate
Povidone-vinylacetate copolymers
Salicylic acid
Simethicone
Tannic acid
Topical starch
Trolamine
Turpentine oil
Zirconium oxide
Zyloxin

(B) *Ingredients—Approved as of* June 4, 2004; June 6, 2005, *for products with annual sales less than $25,000.*

Beeswax
Bismuth subnitrate
Boric acid
Cetyl alcohol
Glyceryl stearate
Isopropyl palmitate
Live yeast cell derivative
Shark liver oil
Stearyl alcohol

* * * * *

(d) * * *

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(2)(i), (a)(3)(i), (a)(4), (a)(6)(i)(A), (a)(6)(ii)(A), (a)(7) (except as covered by paragraph (d)(3) of this section), (a)(8)(i), (a)(10)(i) through (a)(10)(iii), (a)(12)(i) through (a)(12)(iv)(A), (a)(14) through (a)(15)(i), (a)(16) through (a)(18)(i)(A), (a)(18)(ii) (except as covered by paragraph (d)(22) of this section), (a)(18)(iii), (a)(18)(iv), (a)(18)(v)(A), and (a)(18)(vi)(A) of this section.

* * * * *

(32) June 4, 2004, for products subject to paragraphs (a)(18)(i)(B), (a)(18)(v)(B), and (a)(18)(vi)(B) of this section. June 6, 2005, for products with annual sales less than $25,000.

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

■ 3. The authority citation for 21 CFR part 347 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 4. Part 347 is amended by revising the heading for subpart A to read as follows:

Subpart A—General Provisions

* * * * *

■ 5. Section 347.3 is revised to read as follows:

§ 347.3 Definitions.

As used in this part:

Astringent drug product. A drug product applied to the skin or mucous membranes for a local and limited protein coagulant effect.

Lip protectant drug product. A drug product that temporarily prevents dryness and helps relieve chapping of the exposed surfaces of the lips; traditionally called "lip balm."

Poison ivy, oak, sumac dermatitis. An allergic contact dermatitis due to exposure to plants of the genus Rhus (poison ivy, poison oak, poison sumac), which contain urushiol, a potent skin-sensitizer.

Skin protectant drug product. A drug product that temporarily protects injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli, and may help provide relief to such surfaces.

■ 6. Section 347.10 is redesignated as § 347.12 and revised, and subpart B, consisting of a new § 347.10, newly redesignated § 347.12, and new § 347.20, is added to read as follows:

Subpart B—A tiv Ingredients

Sec.
347.10 Skin protectant active ingredients.
347.12 Astringent active ingredients.
347.20 Permitted combinations of active ingredients.

Subpart B—Active Ingredients

§ 347.10 Skin protectant active ingredients.

The active ingredients of the product consist of any of the following, within the concentration specified for each ingredient:

(a) Allantoin, 0.5 to 2 percent.

(b) Aluminum hydroxide gel, 0.15 to 5 percent.

(c) Calamine, 1 to 25 percent.

(d) Cocoa butter, 50 to 100 percent.

(e) Cod liver oil, 5 to 13.56 percent, in accordance with § 347.20(a)(1) or (a)(2), provided the product is labeled so that the quantity used in a 24-hour period does not exceed 10,000 U.S.P. Units vitamin A and 400 U.S.P. Units cholecalciferol.

(f) Colloidal oatmeal, 0.007 percent minimum; 0.003 percent minimum in combination with mineral oil in accordance with § 347.20(a)(4).

(g) Dimethicone, 1 to 30 percent.

(h) Glycerin, 20 to 45 percent.

(i) Hard fat, 50 to 100 percent.

(j) Kaolin, 4 to 20 percent.

(k) Lanolin, 12.5 to 50 percent.

(l) Mineral oil, 50 to 100 percent; 30 to 35 percent in combination with colloidal oatmeal in accordance with § 347.20(a)(4).

(m) Petrolatum, 30 to 100 percent.

(n) [Reserved]

(o) Sodium bicarbonate.

(p) [Reserved]

(q) Topical starch, 10 to 98 percent.

(r) White petrolatum, 30 to 100 percent.

(s) Zinc acetate, 0.1 to 2 percent.

(t) Zinc carbonate, 0.2 to 2 percent.

(u) Zinc oxide, 1 to 25 percent.

§ 347.12 Astringent active ingredients.

The active ingredient of the product consists of any one of the following within the specified concentration established for each ingredient:

(a) Aluminum acetate, 0.13 to 0.5 percent (depending on the formulation and concentration of the marketed product, the manufacturer must provide adequate directions so that the resulting solution to be used by the consumer contains 0.13 to 0.5 percent aluminum acetate).

(b) Aluminum sulfate, 46 to 63 percent (the concentration is based on the anhydrous equivalent).

(c) Witch hazel.

§ 347.20 Permitted combinations of active ingredients.

(a) *Combinations of skin protectant active ingredients.* (1) Any two or more of the ingredients identified in § 347.10(a), (d), (e), (i), (k), (l), (m), and (r) may be combined provided the combination is labeled according to § 347.50(b)(1) and provided each ingredient in the combination is within the concentration specified in § 347.10.

(2) Any two or more of the ingredients identified in § 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r) may be combined provided the combination is labeled according to § 347.50(b)(2) and provided each ingredient in the combination is within the concentration specified in § 347.10.

(3) Any two or more of the ingredients identified in § 347.10(b), (c), (j), (s), (t), and (u) may be combined provided the combination is labeled according to § 347.50(b)(3) and provided each ingredient in the combination is within the concentration specified in § 347.10.

(4) The ingredients identified in § 347.10(f) and (l) may be combined provided the combination is labeled according to § 347.50(b)(7) and provided each ingredient in the combination is within the concentration specified in § 347.10.

(b) *Combinations of skin protectant and external analgesic active ingredients.* Any one (two when required to be in combination) or more of the active ingredients identified in § 347.10(a), (d), (e), (i), (k), (l), (m), and (r) may be combined with any of the following generally recognized as safe and effective external analgesic active ingredients: Single amine and "caine"-type local anesthetics, alcohols and ketones, antihistamines, or any permitted combination of these ingredients, but not with hydrocortisone, provided the product is labeled according to § 347.60(b)(1).

(c) *Combinations of skin protectant and first aid antiseptic active ingredients.* Any one (two when required to be in combination) or more of the active ingredients identified in § 347.10(a), (d), (e), (i), (k), (l), (m), and (r) may be combined with any generally recognized as safe and effective single first aid antiseptic active ingredient, or any permitted combination of these ingredients, provided the product is labeled according to § 347.60(b)(2).

(d) *Combinations of skin protectant and sunscreen active ingredients.* Any one (two when required to be in combination) or more of the skin protectant active ingredients identified in § 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r) may be combined with any generally recognized as safe and effective single sunscreen active ingredient, or any permitted combination of these ingredients, provided the product meets the conditions in § 352.20(b) of this chapter and is labeled according to §§ 347.60(b)(3) and 352.60(b) of this chapter.

■ 7. Section 347.20(d) is stayed until further notice.

■ 8. Section 347.50 is redesignated as § 347.52 and revised, and subpart C, consisting of a new § 347.50, newly redesignated § 347.52, and new § 347.60, is added to read as follows:

Subpart C—Labeling

Sec.
347.50 Labeling of skin protectant drug products.
347.52 Labeling of astringent drug products.
347.60 Labeling of permitted combinations of active ingredients.

Subpart C—Labeling

§ 347.50 Labeling of skin protectant drug products.

A skin protectant drug product may have more than one labeled use and labeling appropriate to different uses may be combined to eliminate duplicative words or phrases as long as the labeling is clear and understandable. When the labeling of the product contains more than one labeled use, the appropriate statement(s) of identity, indications, warnings, and directions must be stated in the labeling.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product with one or more of the following:

(1) *For any product.* "Skin protectant" (optional, may add dosage form, e.g., "cream," "gel," "lotion," or "ointment").

(2) *For products containing any ingredient in § 347.10(b), (c), (j), (s), (t), and (u).* "Poison ivy, oak, sumac drying" (optional, may add dosage form, e.g., "cream," "gel," "lotion," or "ointment").

(3) *For products containing any ingredient in § 347.10(b), (c), (f), (j), (o), (s), (t), and (u).* "Poison ivy, oak, sumac protectant."

(b) *Indications.* The labeling of the product states, under the heading "Uses," one or more of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements, describing

only the uses that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing any ingredient in § 347.10(a), (d), (e), (i), (k), (l), (m), and (r).* The labeling states "temporarily protects minor: [bullet][1] cuts [bullet] scrapes [bullet] burns".

(2) *For products containing any ingredient in § 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r)—(i).* The labeling states "temporarily protects" (which may be followed by: "and helps relieve") "chapped or cracked skin" (which may be followed by: "and lips"). This statement may be followed by the optional statement: "helps protect from the drying effects of wind and cold weather". [If both statements are used, each is preceded by a bullet.]

(ii) *For products formulated as a lip protectant.* The labeling states "temporarily protects" (which may be followed by: "and helps relieve") "chapped or cracked lips". This statement may be followed by the optional statement: "helps protect lips from the drying effects of wind and cold weather". [If both statements are used, each is preceded by a bullet.]

(3) *For products containing any ingredient in § 347.10(b), (c), (j), (s), (t), and (u).* The labeling states "dries the oozing and weeping of poison: [bullet] ivy [bullet] oak [bullet] sumac".

(4) *For products containing colloidal oatmeal identified in § 347.10(f).* The labeling states "temporarily protects and helps relieve minor skin irritation and itching due to: [select one or more of the following: '[bullet] rashes' '[bullet] eczema' '[bullet] poison ivy, oak, or sumac' '[bullet] insect bites']."

(5) *For products containing sodium bicarbonate identified in § 347.10(o).* The labeling states "temporarily protects and helps relieve minor skin irritation and itching due to: [bullet] poison ivy, oak, or sumac [bullet] insect bites".

(6) *For products containing topical starch identified in § 347.10(q).* The labeling states "temporarily protects and helps relieve minor skin irritation".

(7) *For products containing the combination of ingredients in § 347.20(a)(4).* The labeling states "temporarily protects and helps relieve minor skin irritation and itching due to: [select one or more of the following: 'rashes' or 'eczema']." [If both conditions are used, each is preceded by a bullet.]

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "For external use only" in accord with § 201.66(c)(5)(i) of this chapter. For products containing only mineral oil in § 347.10(l) or sodium bicarbonate in § 347.10(o), this warning may be omitted if labeling for oral use of the product is also provided.

(2) "When using this product [bullet] do not get into eyes".

(3) "Stop use and ask a doctor if [bullet] condition worsens [bullet] symptoms last more than 7 days or clear up and occur again within a few days".

(4) For products labeled according to § 347.50(b)(1) or (b)(2): "Do not use on [bullet] deep or puncture wounds [bullet] animal bites [bullet] serious burns".

(5) For products containing colloidal oatmeal identified in § 347.10(f) when labeled for use as a soak in a tub. "When using this product [bullet] to avoid slipping, use mat in tub or shower".

(6) For powder products containing kaolin identified in § 347.10(j) or topical starch identified in § 347.10(q)—(i) "Do not use on [bullet] broken skin".

(ii) "When using this product [bullet] keep away from face and mouth to avoid breathing it".

(7) For products containing colloidal oatmeal identified in § 347.10(f) or sodium bicarbonate identified in § 347.10(o) when labeled for use as a soak, compress, or wet dressing. "When using this product [bullet] in some skin conditions, soaking too long may overdry".

(d) *Directions.* The labeling of the product contains the following statements, as appropriate, under the heading "Directions":

(1) *For products labeled according to § 347.50(b)(1), (b)(2), (b)(3), (b)(5), or (b)(6).* The labeling states "apply as needed".

(2) *For products containing colloidal oatmeal identified in § 347.10(f)—(i) For products requiring dispersal in water.* The labeling states "[bullet] turn warm water faucet on to full force [bullet] slowly sprinkle" (manufacturer to insert quantity to be used) "of colloidal oatmeal directly under the faucet into the tub or container [bullet] stir any colloidal oatmeal settled on the bottom".

(A) *For products used as a soak in a bath.* The manufacturer must provide adequate directions to obtain a solution containing a minimum of 0.007 percent colloidal oatmeal or 0.003 percent colloidal oatmeal in the oilated form for a tub bath, sitz bath, or infant bath, or a minimum of 0.25 percent colloidal oatmeal for a foot bath. "For use as a soak in a bath: [bullet] soak affected area for 15 to 30 minutes as needed, or as directed by a doctor [bullet] pat dry (do not rub) to keep a thin layer on the skin".

(B) *For products used as a compress or wet dressing.* The manufacturer must provide adequate directions to obtain a solution containing a minimum of 0.25 percent colloidal oatmeal. "For use as a compress or wet dressing: [bullet] soak a clean, soft cloth in the mixture [bullet] apply cloth loosely to affected area for 15 to 30 minutes [bullet] repeat as needed or as directed by a doctor [bullet] discard mixture after each use".

(ii) *For topical products intended for direct application.* The labeling states "apply as needed".

(3) *For products containing sodium bicarbonate identified in § 347.10(o).* The labeling states "[bullet] adults and children 2 years of age and over:"

(i) The labeling states "For use as a paste: [bullet] add enough water to the sodium bicarbonate to form a paste [bullet] apply to the affected area of the skin as needed, or as directed by a doctor".

(ii) The labeling states "For use as a soak in a bath: [bullet] dissolve 1 to 2 cupfuls in a tub of warm water [bullet] soak for 10 to 30 minutes as needed, or as directed by a doctor [bullet] pat dry (do not rub) to keep a thin layer on the skin".

(iii) The labeling states "For use as a compress or wet dressing: [bullet] add sodium bicarbonate to water to make a mixture in a container [bullet] soak a clean, soft cloth in the mixture [bullet] apply cloth loosely to affected area for 15 to 30 minutes [bullet] repeat as needed or as directed by a doctor [bullet] discard mixture after each use".

(iv) Any of the directions in paragraphs (d)(3)(i), (d)(3)(ii), or (d)(3)(iii) of this section shall be followed by the statement: "[bullet] children under 2 years: ask a doctor".

(4) *For products containing aluminum hydroxide gel identified in § 347.10(b).* The labeling states "[bullet] children under 6 months: ask a doctor".

(5) *For products containing glycerin identified in § 347.10(h).* The labeling states "[bullet] children under 6 months: ask a doctor".

(6) *For products containing zinc acetate identified in § 347.10(s).* The labeling states "[bullet] children under 2 years: ask a doctor".

[1] *See* § 201.66(b)(4) of this chapter for definition of bullet symbol.

(e) *Products formulated and labeled as a lip protectant and that meet the criteria established in § 201.66(d)(10) of this chapter.* The title, headings, subheadings, and information described in § 201.66(c) of this chapter shall be printed in accordance with the following specifications:

(1) The labeling shall meet the requirements of § 201.66(c) of this chapter except that the title, headings, and information described in § 201.66(c)(1), (c)(3), (c)(6), and (c)(7) may be omitted, and the headings, subheadings, and information described in § 201.66(c)(2), (c)(4), and (c)(5) may be presented as follows:

(i) The active ingredients (§ 201.66(c)(2) of this chapter) shall be listed in alphabetical order.

(ii) The heading and the indication required by § 201.66(c)(4) may be limited to: "Use [in bold type] helps protect" (which may be followed by "and relieve") "chapped lips".

(iii) The "external use only" warning in § 347.50(c)(1) and in § 201.66(c)(5)(i) of this chapter may be omitted. The warnings in § 347.50(c)(2) and (c)(4) are not required and the warning in § 347.50(c)(3) may be revised to read "Stop use and ask a doctor if condition lasts more than 7 days."

(iv) The subheadings in § 201.66(c)(5)(iii) through (c)(5)(vi) of this chapter may be omitted, provided the information after the heading "Warning" contains the warning in § 347.50(e)(1)(iii).

(v) The warnings in § 201.66(c)(5)(x) of this chapter may be omitted.

(2) The labeling shall be printed in accordance with the requirements of § 201.66(d) of this chapter except that any requirements related to § 201.66(c)(1), (c)(3), (c)(6), and (c)(7), and the horizontal barlines and hairlines described in § 201.66(d)(8), may be omitted.

(f) *Products containing only cocoa butter, petrolatum, or white petrolatum identified in § 347.10(d), (m), and (r), singly or in combination with each other, and marketed other than as a lip protectant.* (1) The labeling shall meet the requirements of § 201.66(c) of this chapter except that the headings and information described in § 201.66(c)(3) and (c)(7) may be omitted, and the headings, subheadings, and information described in § 201.66(c)(2), (c)(4), and (c)(5) may be presented as follows:

(i) The active ingredients (§ 201.66(c)(2) of this chapter) shall be listed in alphabetical order.

(ii) The heading and the indication required by § 201.66(c)(4) of this chapter may be limited to "Use [in bold type] helps protect minor cuts and burns" or "Use [in bold type] helps protect chapped skin" or "Use [in bold type] helps protect minor cuts and burns and chapped skin".

(iii) The warning in § 347.50(c)(3) may be revised to read "*See* a doctor if condition lasts more than 7 days."

(iv) The subheadings in § 201.66(c)(5)(iv) through (c)(5)(vii) of this chapter may be omitted, provided the information after the heading "Warnings" contains the warnings in § 347.50(c)(2), (c)(4), and (f)(1)(iii).

(2) The labeling shall be printed in accordance with the requirements of § 201.66(d) of this chapter except that any requirements related to § 201.66(c)(3) and (c)(7) may be omitted.

§ 347.52 Labeling of astringent drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "astringent."

(b) *Indications.* The labeling of the product states, under the heading "Uses" any of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in this paragraph (b) may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition of section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing aluminum acetate identified in § 347.12(a).* "For temporary relief of minor skin irritations due to: [select one or more of the following: 'poison ivy,' 'poison oak,' 'poison sumac,' 'insect bites,' 'athlete's foot,' or 'rashes caused by soaps, detergents, cosmetics, or jewelry']."

(2) *For products containing aluminum sulfate identified in § 347.12(b) for use as a styptic pencil.* "Stops bleeding caused by minor surface cuts and abrasions as may occur during shaving."

(3) *For products containing witch hazel identified in § 347.12(c).* "Relieves minor skin irritations due to: [select one or more of the following: 'insect bites,' 'minor cuts,' or 'minor scrapes']." [If more than one condition is used, each is preceded by a bullet.]

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "For external use only. Avoid contact with the eyes."

(2) *For products containing aluminum acetate identified in § 347.12(a) or witch hazel identified in § 347.12(c).* "If condition worsens or symptoms persist for more than 7 days, discontinue use of the product and consult a" [select one of the following: 'physician' or 'doctor']."

(3) *For products containing aluminum acetate identified in § 347.12(a) used as a compress or wet dressing.* "Do not cover compress or wet dressing with plastic to prevent evaporation."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *For products containing aluminum acetate identified in § 347.12(a)*—(i) *For products used as a soak.* "For use as a soak: Soak affected area in the solution for 15 to 30 minutes. Discard solution after each use. Repeat 3 times a day."

(ii) *For products used as a compress or wet dressing.* "For use as a compress or wet dressing: saturate a clean, soft white cloth (such as a diaper or torn sheet) in the solution, gently squeeze, and apply loosely to the affected area. Saturate the cloth in the solution every 15 to 30 minutes and apply to the affected area. Discard solution after each use. Repeat as often as necessary."

(2) *For products containing aluminum sulfate identified in § 347.12(b) for use as a styptic pencil.* "Moisten tip of pencil with water and apply to the affected area. Dry pencil after use."

(3) *For products containing witch hazel identified in § 347.12(c).* "Apply to the affected area as often as necessary."

§ 347.60 Labeling of permitted combinations of active ingredients.

The statement of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(b) *Indications.* The labeling of the product states, under the heading

"Uses," the indication(s) for each ingredient in the combination as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (b). Other truthful and nonmisleading statements, describing only the indications for use that have been established in the applicable OTC drug monographs or listed in this paragraph (b) may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act. In addition to the required information identified in this paragraph (b), the labeling of the product may contain any of the "other allowable statements" that are identified in the applicable monographs, provided such statements are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(1) *Combinations of skin protectant and external analgesic active ingredients in § 347.20(b).* In addition to any or all of the indications for skin protectant drug products in § 347.50(b)(1), any or all of the allowable indications for external analgesic drug products may be used if the product is labeled for concurrent symptoms.

(2) *Combinations of skin protectant and first aid antiseptic active ingredients in § 347.20(c).* In addition to any or all of the indications for skin protectant drug products in § 347.50(b)(1), the required indications for first aid antiseptic drug products should be used.

(3) *Combinations of skin protectant and sunscreen active ingredients in § 347.20(d).* In addition to any or all of the indications for skin protectant drug products in § 347.50(b)(2)(i), the required indications for sunscreen drug products should be used and any or all of the additional indications for sunscreen drug products may be used.

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings section of the applicable OTC drug monographs unless otherwise stated in this paragraph (c).

(1) *For combinations containing a skin protectant and a sunscreen identified in §§ 347.20(d) and 352.20(b).* The warnings for sunscreen drug products in § 352.60(c) of this chapter are used.

(2) [Reserved]

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (d). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

(1) *For combinations containing a skin protectant and a sunscreen identified in §§ 347.20(d) and 352.20(b).* The directions for sunscreen drug products in § 352.60(d) of this chapter are used.

(2) [Reserved]

PART 352—SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

■ 9. The authority citation for 21 CFR part 352 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 10. The stay of 21 CFR part 352 published at 66 FR 67485, December 31, 2001, is lifted.

■ 11. Section 352.20 is amended by adding paragraph (b) to read as follows:

§ 352.20 Permitted combinations of active ingredients.

* * * * *

(b) *Combinations of sunscreen and skin protectant active ingredients.* Any single sunscreen active ingredient or any permitted combination of sunscreen active ingredients when used in the concentrations established for each ingredient in § 352.10 may be combined with one or more skin protectant active ingredients identified in § 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r) of this chapter. The concentration of each sunscreen active ingredient must be sufficient to contribute a minimum SPF of not less that 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2, and the product must be labeled according to § 352.60.

■ 12. Section 352.52 is amended by revising the heading in paragraphs (c)(2) and (d)(4) and by revising paragraphs (f)(1)(ii) and (f)(1)(vi) to read as follows:

§ 352.52 Labeling of sunscreen drug products.

* * * * *

(c) * * *

(2) *For products containing any ingredient identified in § 352.10 marketed as a lip protectant or lipstick.*

* * *

(d) * * *

(4) *For products marketed as a lip protectant or lipstick.* * * *

* * * * *

(f) * * *

(1) * * *

(ii) The heading and the indication required by § 201.66(c)(4) of this chapter may be limited to: "Use [in bold type] helps protect against sunburn." For a lip protectant product, the heading and the indication required by § 201.66(c)(4) may be limited to: "Use [in bold type] helps protect against sunburn and chapped lips."

* * * * *

(vi) For a lip protectant product or lipstick, the warnings "Keep out of eyes" in § 352.52(f)(1)(iv) and "Keep out of reach of children" in § 352.52(f)(1)(v) and the directions in § 352.52(d) may be omitted.

* * * * *

13. Section 352.60 is amended by revising paragraphs (b)(2), (c), and (d) to read as follows:

§ 352.60 Labeling of permitted combinations of active ingredients.

* * * * *

(b) * * *

(2) For permitted combinations containing a sunscreen and a skin protectant identified in § 352.20(b), any or all of the applicable indications for sunscreens in § 352.52(b) and the indication for skin protectants in § 347.50(b)(2)(i) of this chapter should be used. For products marketed as a lip protectant, the indication in § 352.52(f)(1)(ii) should be used.

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings section of the applicable OTC drug monographs, except that the warning for skin protectants in § 347.50(c)(3) of this chapter is not required for permitted combinations containing a sunscreen and a skin protectant identified in § 352.20(b). For products marketed as a lip protectant or lipstick, § 352.52(f)(1)(iii), (f)(1)(iv) (except

"Keep out of eyes," which may be omitted), and (f)(1)(vi) apply.

(d) *Directions.* The labeling of the product states, under the heading "directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient. For permitted combinations containing a sunscreen and a skin protectant identified in § 352.20(b), the directions for sunscreens in § 352.52(d) should be used. For products marketed as a lip protectant or lipstick, § 352.52(d)(4) applies.

■ 14. Part 352 is stayed until further notice.

Dated: May 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–13751 Filed 6–3–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 524

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Combe, Inc., to Farnham Companies, Inc.

DATES: This rule is effective June 4, 2003.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967; e-mail: dnewkirk@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Combe, Inc., 1101 Westchester Ave., White Plains, NY 10604, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 5–236 for SULFODENE Medication for Dogs to Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013–3928. Accordingly, the agency is amending the regulations in 21 CFR 524.1376 to reflect the transfer of ownership.

Following this change of sponsorship, Combe, Inc., is no longer the sponsor of any approved application. Accordingly, § 510.600(c) is being amended to remove the entries for Combe, Inc.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 524

Animal drugs.

■ Therefore, under the Federal Food, Drug and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 524 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended].

■ 2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for "Combe, Inc." and in the table in paragraph (c)(2) by removing the entry for "011509".

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.1580b [Amended]

■ 4. Section 524.1376 *2–Mercaptobenzothiazole solution* is amended in paragraph (b) by removing "011509" and by adding in its place "No. 017135".

Dated: May 19, 2003.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 03–14107 Filed 6–3–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9048]

Guidance Under Section 1502; Suspension of Losses on Certain Stock Dispositions; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document corrects temporary regulations (TD 9048), which was published in the **Federal Register** on Friday, March 14, 2003 (68 FR 12287). The temporary regulations redetermine the basis of stock of a subsidiary member of a consolidated group immediately prior to certain transfers of such stock and certain deconsolidations of a subsidiary member and also suspend certain losses recognized on the disposition of stock of a subsidiary member.

DATES: This correction is effective on March 14, 2003.

FOR FURTHER INFORMATION CONTACT: Aimee K. Meacham at (202) 622–7530 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations that are the subject of this correction are under section 1502 of the Internal Revenue Code.

Need for Correction

As published, TD 9048 contains an error which may prove to be misleading and is in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

■ Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *